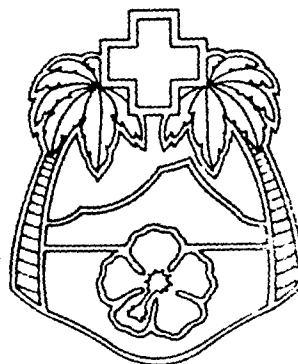


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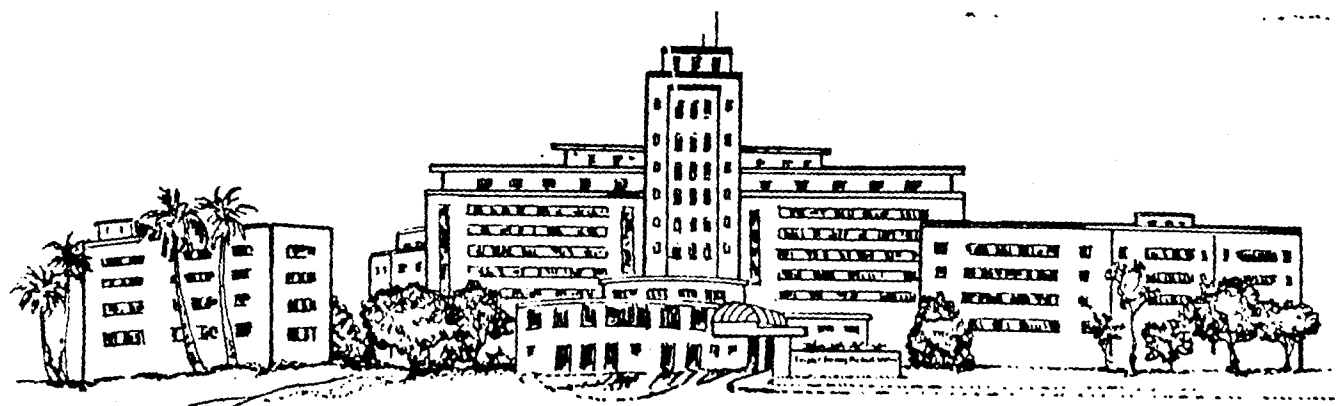
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CLINICAL INVESTIGATION PROGRAM

REPORTS CONTROL SYMBOL MED-300 (R1)

FISCAL YEAR 1988

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20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies those individuals who are conducting investigative protocols at Tripler Army Medical Center. An abstract of each project giving abbreviated technical objectives, methods, and progress is presented. Keywords: Dentistry, Clinical medicine, Military Medicine, Medical Research, Nursing, Obstetrics, Gynecology, Pathology, Medical Laboratories, Pediatrics, Preventive medicine, Surgery, Oncology.		

A N N U A L P R O G R E S S R E P O R T

DEPARTMENT OF CLINICAL INVESTIGATION
Reports Control Symbol MED-300(R-1)

FISCAL YEAR 1988
1 October 1988

DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER
Tripler AMC, Hawaii 96859-5000

The opinions and assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

FOREWORD

Fiscal Year 1988 has been literally a turning point in Clinical Investigation here. The Commanding General, MG John Major, initiated a series of meetings that defined a new direction and dimension for Clinical Investigation in the Army. Rather than a neglected and uninspired hobby shop for amateur efforts by clinicians with no research training or focus, Clinical Investigation at Tripler was ordered to become a command guided and supported program in the tradition of the finest research institutes. Tripler has started to recognize and build on the world-class research effort developed here quietly over the years by Dr. John Claybaugh. That research program has fought successfully for national research funds and recognition, including visiting professors on sabbatical, and is being transformed into the supporting academic focus potentially important to the future of several GME programs. Payoff already has included multiple studies involving hospital staff in national lead research, presentations and publications. The most marked accomplishment has been approval of a Neonatology fellowship with research here supporting joint clinical rotations at Tripler and Kapiolani Women's and Children's Hospital.

With this as a model, and as a proof that the direction was a good one, command guidance and support led to plans for the people, space and funds required to turn Tripler into one of the country's great medical centers over the next several years. I was asked to integrate this into a comprehensive academic goal integral to Triplers Action Plan 1990 and beyond. That goal includes "cloning" the already successful research in Physiology; duplicating that success in other areas likely to be major pay-off areas of medical advancement over the next decades. New starts have begun already, notably with support of COL Hill, Chief of Pathology, who underwrote research with funds as well as management emphasis.

It was also a year for extraordinary help from Logistics under the leadership of COL Ed Gayagas, from the TAMC Comptroller LTC Allan King, and (most importantly) from HSC staff: LTC Rob McAuley, LTC Loren Quigg, and Vera Neil. Our MEDCASE, with great help from Walter Reed contracting staff including Donna Hutton and Al Bariatti, was rich with equipment, including a mainframe computer that puts us in a national lead posture in quality of automation support.

Most powerfully of all, Tripler Clinical Investigation was given an image that sustains: of research being the third (balancing) leg of a symbolic stool representing our mission of readiness: patient care for readiness today, teaching for readiness tomorrow, and research for readiness extending into the future. And that, more than for everything else, is why this volume is dedicated to General Major.



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DEPARTMENT OF CLINICAL INVESTIGATION
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: To sponsor clinical investigation, in compliance with applicable laws, regulations and policies, to increase the academic professional stature of the MEDCEN.

B. TECHNICAL APPROACH: 1) Renew research documentation and advise the Commander and his institutional committees on matters pertaining to clinical investigation, and 2) Provide consultative and collaborative support to approved investigations.

C. STAFFING:

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Kyser, Kay A.	COL	61F9B	Chief
McCullen, Albert H.	MAJ	64C9B	Chief, Veterinary Service
Freund, Beau J.	CPT	68J00	Research Physiologist
Conceicao, Mary Lou	SSG	92B30	NCOIC
Leininger, Harold V.	SSG	91T30	Animal Care Specialist
Brady, Anne V.	SGT	01H2R	Biological Science Asst
Pina, Elsa L.	SPC	92B10	Medical Laboratory Specialist
Lauersen, Sandra J.	SPC	91T10	Animal Care Specialist
Claybaugh, John R.	GM14	00413	Chief, Physiology Service
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Yee, Denise M. L.	WG04	03566	Animal Caretaker
Kullama, Linda K.*			Post Doctoral Fellow
Dice, Margaret S.**			Biological Laboratory Tech
Eichinger, Mark R.***			Biological Laboratory Tech
Shizuru, Everett M.****			Biological Laboratory Tech
Griffith, Robert B.****			Biological Laboratory Tech
Keeler, Ralph			Visiting Professor(Sabbatical)
Wilson, Nadine			Visiting Professor(Sabbatical)

*American Heart Assn.(Kapiolani Hospital)

**NIH Grant

***Leahi Trust(University of Hawaii)

****VA/DOD(Educational Contract)

D. FUNDING:

Funding Type	1987	USMRDC Grant 1987	1988	USMRDC Grant 1988
Civilian personnel including benefits	\$244,501	\$ 27,043	\$279,543	\$ 35,027
Consumable supplies	109,842	4,090	146,620	145
Civilian contracts including consultants	27,433		36,375	9,600
TDY	26,904		25,915	634
Publications	3,208		3,126	
Noninvestment equipment (Minor MEDCASE)	1,390		20,207	
Other OMA Trans & Taxes Rentals	473		17	
OMA Total	413,751	31,133	612,131	45,406
MEDCASE	65,890		280,559	
Military	428,712		420,178	
Pathology Funds			*319,000	
TOTAL	\$908,353	31,133	2,143,671	45,406

* The approximate costs used within the Department of Pathology to support research efforts: Civilian Pay: \$114,000.; MD/PhD Military Pay: Approx 2.2 manyears, \$125,000.; Expendable Supplies: \$68,000.; Supplemental Care purchase of services performed by commercial reference laboratories: \$11,000.

E. PROGRESS: This increase in support is the start of a reversal of a decade of decline. Issues of logistic support, space, people, and policy are all being addressed with solutions programmed over the next three years.

F. PROBLEMS: See progress.

HISTORY OF TAMC PROTOCOLS, PRESENTATIONS, AND PUBLICATIONS

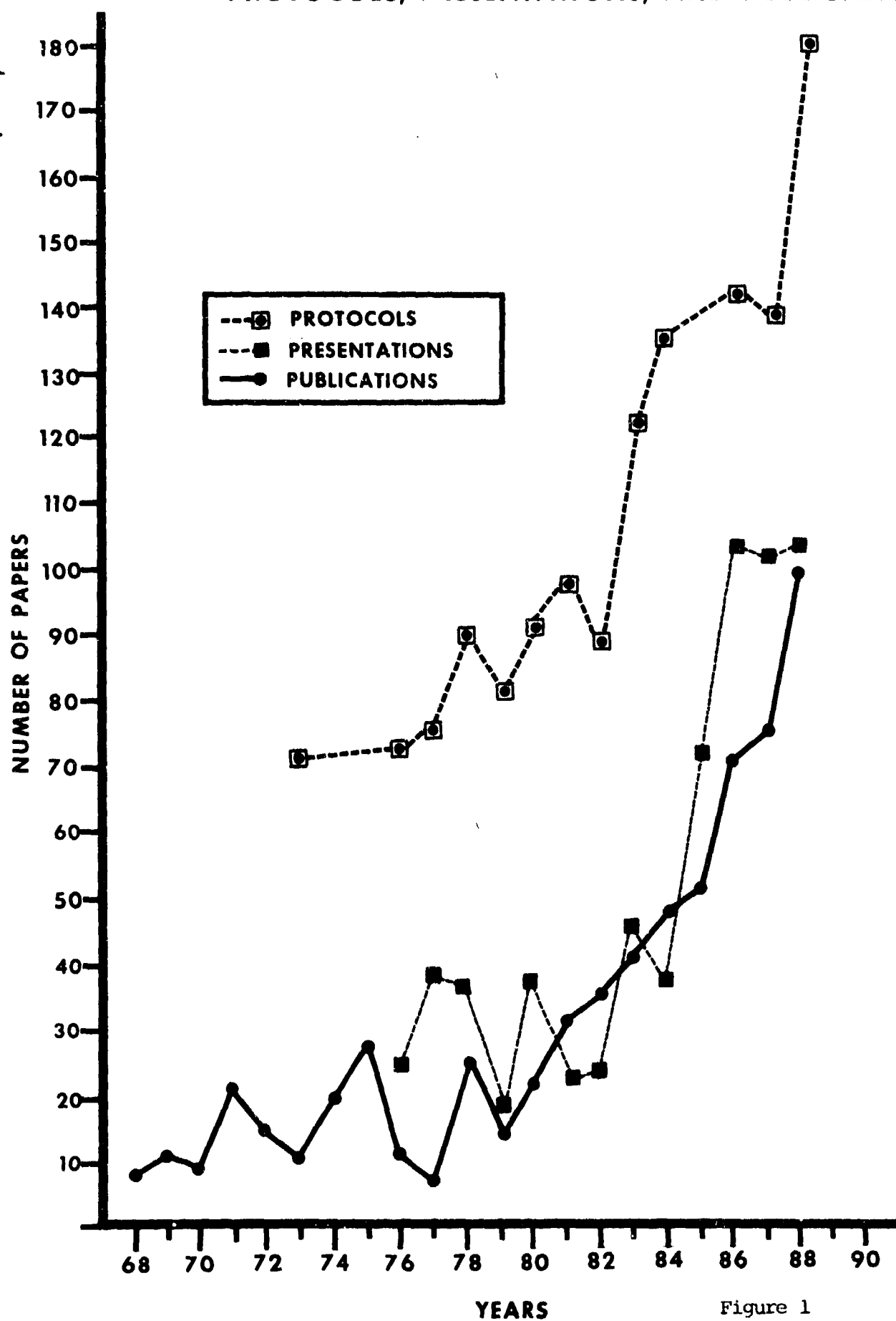


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DEPARTMENT OF CLINICAL INVESTIGATION

CLAYBAUGH JOHN R: "Hormonal regulation of fluid and electrolytes: environmental effects"/Las Vegas, NEV (30Apr-5May88); DB Dill Environmental Symposium & Ann Fed of Am Soc for experimental Biology

CLAYBAUGH JOHN R, CUCINELL SA, EVANS WS, ASKEW EW, STOKES WK, WADE CE, KEARNEY JJ: "Physiology differences between acute mountain sickness, high altitude pulmonary edema, and high altitude retinopathy"/Ann Intern Med Submitted for Cucinell by Claybaugh

CLAYBAUGH JOHN R, SAGAWA S, SHIRAKI K, PARK Y S, MOHRI M, HONG S K: "Plasma atrial natriuretic factor concentration does not increase during a 31 ATA saturation dive: implications of central volume receptors in the hyperbaric diuresis"/*Yokosuka, Japan (4-6Nov87); 9th UJNR

FREUND BEAU J, CLAYBAUGH JOHN R, HASHIRO GLENN M, WORTHAM DALE C: "Hormonal and renal responses to a reduction in plasma osmolality: further evidence of a water conservation in endurance trained men"/Las Vegas, NE (30Apr-5May88), ann Fed of Am Soc for ex perimental Biology

FREUND BEAU J, HASHIRO GLENN, BUONO MICHAEL J, CLAYBAUGH JOHN R, CHRISNEY S: "Endocrine and electrolyte responses during and following a marathon in young versus middle aged runners" abstract/Dallas, Tx (25-28May88); Am College of Sports Med Mtg

FREUND BEAU J, WADE CHARLES, CLAYBAUGH JOHN R: "Effects of exercise on atrial natriuretic factor: implications to fluid homeostasis"/Sports Med Int J Appli Med Sci in Sports and Exercise

KYSER KAY A: "Computer-assisted microscopy in human breast cancer research (use of image graphics in medicine)/HI (2Jun88); Hi Intergov't Info Processing Council Mtg

KYSER KAY A: "Ethical and legal considerations in clinical research"/HI Annual Nrsg Research Day

ROMASH MICHAEL M, HENNINGSSEN HAROLD J, CLAYBAUGH JOHN R: "Knee braces - comparative functional testing"/J Bone Joint Surg

UYEHARA CATHERINE FT, CLAYBAUGH JOHN R: "Vasopressin metabolism in the amniotic sac of the fetal guinea pig"/Endocrinology

FAMILY PRACTICE

BAILEY BRUCE O: "Pheochromocytoma: report of a fatal case in a young soldier and review of the literature"/Salt Lake City, Utah (27Mar-1Apr88); 14th ann mtg of Uniformed Svcs Acad of Fam Physicians

DUNN JAMES F: "Pseudofolliculitis barbae"/Am Fam Physician

DEPARTMENT OF MEDICINE

BASS JAMES W, PALMER STEPHEN R, MANDOJANA RICARDO, WITTNER ROBERT R: "Tinea nigra palmaris and plantaris: A black fungus producing black spots on the palms and soles"/Pediatr Infect Dis

BERENBERG JEFFREY L, ENZENAUER RAYMOND: "Progressive warfarin anticoagulation in protein C deficiency: a therapeutic strategy"/Honolulu, HI (25-26Mar88); Ann regional mtg of Hi Chapter Am College of Physicians

BERG BENJAMIN W, DILLARD TA, MEHM WJ, DOOLEY JW, RAJAGOPAL KR: "Oxygen supplementation during altitude exposure in COPD"/Anaheim, CA (3-7Oct88); Am College of Chest Physicians Scientific Assembly

BORNEMANN MICHAEL: Ltr to the Ed (re: thyroiditis and seatbelt use)/N Engl J Med

BORNEMANN MICHAEL, GEORGITIS WILLIAM J: "TRH testing: an inadequate confirmatory test for subclinical hypothyroidism"/ (10Jun88); Endocrine So ann mtg

CHETHAM STEVEN T, BERENBERG JEFFREY L: "Disseminated intravascular coagulation and thrombosis in a patient with hereditary factor IX deficiency receiving prothrombin complex concentrates"/Honolulu, HI (25-26Mar88); Ann regional mtg Hi Chapter Am College of Physicians

FENGLER SCOTT A, BERENBERG JEFFREY L, LEE MARGARET Y-T: "Disseminated coagulopathies and advanced malignancies"/Cancer

FREUND BEAU J, CLAYBAUGH JOHN R, HASHIRO GLENN M, WORTHAM DALE C: "Hormonal and renal responses to a reduction in plasma osmolality: further evidence of a water conservation in endurance trained men"/Las Vegas, NE (30Apr-5May88), ann Fed of Am Soc for experimental Biology

HERNANDEZ ENRIQUE, MIYAZAWA KUNIO, BERENBERG JEFFREY: "Cervical adenocarcinoma among cytologically screened and unscreened women in the Pacific"/Gynecol Oncol

JONES GARY P, WATTS DAVID M, BOWMAN GREG A, OLSEN JOHN D: "Giant benign mesothelioma"/Chest

LEE MARGARET Y-T, STAPLETON LUKE M, WOODS JOSEPH C, CHO JOHN M: "Primary non-Hodgkin's lymphoma of the spleen: a case report"/Contemporary Surgery

MELICK LARRY B, MORGAN J ALAN: "Presentations of acute phenytoin overdose"/Am J Emergency Medicine

MELICK LARRY B, REESOR KENNETH C: "Spiral tibial fractures of childhood"/Emergency Medicine

SHERMAN KENNETH E, BORNEMANN MICHAEL: "Letter to Editor" re: hypoglycemic unawareness during treatment with amitriptyline/Annals of Internal Medicine

SHERMAN KENNETH E, JONES CHARLES C: "Hepatotoxicity associated with piroxicam in a patient with chronic hepatitis B infection"/Am J Gastroenterol

SHERMAN KENNETH E, JONES CHARLES C, GOLDSTEIN ALLAN: "Serum thymosin alpha-1 levels in patients chronically infected with hepatitis B"/Gastroenterology

SODHI VIMAL K, SAUSKER WILLIAM F: "Dermatoses of Pregnancy"/Am Fam Physician

UPHOUSE WILLIAM J, MARTIN RUSSELL R, LEE MARGARET Y-T, RONQUILLO AIDA P, COOPER GARY L, MCCORMACK DANIEL R: "Rapid remission of a large pleomorphic rhabdomyosarcoma with radiation and a novel schedule of simultaneous high dose cisplatin"/Cancer

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

ANDREWS STEPHEN J, MIYAZAWA KUNIO, MOAD JOHN C: "Papillary peritoneal tumor metastatic to the ovary: a case report"/San Antonio TX (6-10Nov83); Armed Forces Am College of OB-GYN

ANDREWS STEPHEN, HERNANDEZ ENRIQUE, MIYAZAWA KUNIO: "Paired papanicolaou smears in the evaluation of atypical squamous cells" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

ANDREWS STEPHEN, MIYAZAWA KUNIO: "The significance of a negative papanicolaou smear with hyperkeratosis or parakeratosis" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

BORK MICHAEL D, LETTERIE GERARD S, MIYAZAWA KUNIO: "Intermittent ovarian failure (a report of two cases)" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

BRUNER JOSEPH P, CHEEK THEODORE, FOROUZAN IRAZ, SAMUELS PHILIP: "Effect of epidural anesthesia for repeat cesarean section on umbilical and arcuate artery flow velocity waveforms" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

BRUNER JOSEPH P, FOROUZAN IRAJ: "Effect of intravenous magnesium sulfate on umbilical and arcuate artery doppler flow velocity waveforms" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

BRUNER JOSEPH P, HUME RODERICK, MASLOW ARTHUR: "Changing patterns of obstetric practice in tertiary care medical centers in the United States Military: 1982-1987 Association of military perinatologists of the United States: Ampus Protocol #1" abstract /San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

BRUNER JOSEPH P, MENARD KATHRYN, SAMUELS PHILIP, HERMAN CHERYL: "Perinatal effects of acute cocaine abuse in pregnancy" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

BRUNER JOSEPH P, YEOMANS EDWARD R: "Maternal fetal medicine review" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

BYRON JOHN W, FUJIYOSHI CAROL A, MIYAZAWA KUNIO: "Evaluation of direct trocar insertion technique at laparoscopy"/* Boston, MA (1-5May88), ann ACOG Clin Mtg

FASOLAK WALTER, LETTERIE GERARD S, MIYAZAWA KUNIO: "Laparoscopy and minilaparotomy as operative management of ectopic pregnancy" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

GAYLORD ROSE S, LETTERIE GERARD S, MIYAZAWA KUNIO: "Pregnancy rates using oil-based and water-based contrast medium in the evaluation of tubal patency"/San Antonio TX (6-10Nov88); Armed Forces Am College of OB-GYN

HERNANDEZ ENRIQUE, MIYAZAWA KUNIO, BERENBERG JEFFREY: "Cervical adenocarcinoma among cytologically screened and unscreened women in the Pacific"/Gynecol Oncol

HIBBERT MILO L, KOPELMAN JEROME N, MIYAZAWA KUNIO: "Unilateral tubal twin gestation" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

HIBBERT MILO, MIYAZAWA KUNIO: "The use of cystoscopy immediately after vaginal hysterectomy to detect urinary tract injury" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

KOPELMAN JEROME N, MIYAZAWA KUNIO: "Topical 5 fluorouracil treatment in early pregnancy: a report of two cases" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

KOPELMAN JEROME N, MIYAZAWA KUNIO: "Multifetal pregnancies: The tripler experience" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

KOPELMAN JEROME N, WALTON DAVID, WILSON JAMES, MIYAZAWA KUNIO: "Antepartum diagnosis of arthrogryposis associated with trisomy 18" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

KOPELMAN JEROME N, WILSON JAMES, MIYAZAWA KUNIO: "Hepatosplenic schistosomiasis in pregnancy: Report of a case and review of the literature" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

LETTERIE GERARD S, BORK MICHAEL D, MIYAZAWA KUNIO: "Intermittent ovarian failure: report of two cases"/Am J Obstet Gynecol

LETTERIE GERARD S, BYRON JOHN W, SALMINEN ERIC R, MIYAZAWA KUNIO: "Laparoscopic management of fallopian tube prolapse"/Obstet Gynecol

LETTERIE GERARD S, FASOLAK WALTER S, MIYAZAWA KUNIO: "Laparoscopy and minilaparotomy as operative management of ectopic pregnancy"/J Reprod Med

LETTERIE GERARD S, HIBBERT MILO L, RAMIREZ EDWARD J, MIYAZAWA KUNIO: "Expectant management of abnormal titers of human chorionic gonadotropin (hCG) during the first trimester of pregnancy"/Atlanta GA (8-13Oct88); Am Fertility Soc Mtg

LETTERIE GERARD S, KLEIN THOMAS A, WINKEL CRAIG A: "Modulation of hepatic cholesterol metabolism by ethinyl estradiol and norgestrel"/Contraception

LETTERIE GERARD S, MIYAZAWA KUNIO: "Simple modification of an intrauterine manipulator"/Obstet Gynecol

LETTERIE GERARD S, ROSE SCOTT, MIYAZAWA KUNIO: "Heterophile antibodies and false-positive assays for human chorionic gonadotropin"/Am J Obstet Gynecol

LETTERIE GERARD S, VAUSS N, MIYAZAWA KUNIO: "Mullerian tract abnormalities and associated auditory deficiencies" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

LETTERIE GERARD S, WILSON JAMES, MIYAZAWA KUNIO: "Magnetic resonance imaging of mullerian tract abnormalities"/Fertil Steril

LETTERIE GERARD S, WROBLE LORI A, MIYAZAWA KUNIO: "Expectant management of persistent ectopic pregnancy"/Contraception

MARKENSON GLENN, HIBBERT MILO, LETTERIE GERARD S, KOPELMAN JEROME, MIYAZAWA KUNIO: "A case of twin tubal gestation associated with appropriately rising human chorionic gonadotropin concentration"/San Antonio TX (6-10Nov88); Armed Forces Am College of OB- GYN

MIYAZAWA KUNIO, ANDREWS STEPHEN, HERNANDEZ ENRIQUE: "Paired papanicolaou smears in the evaluation of atypical squamous cells"/Obstet Gynecol; *Armed Forces ACOG mtg

PERKINS RICK L, HERNANDEZ ENRIQUE, MIYAZAWA KUNIO: "Ovarian endodermal sinus tumor during pregnancy"/Mil Med

RAMIREZ EDWARD J, HERNANDEZ ENRIQUE, MIYAZAWA KUNIO: "Cervical conization findings in women with dysplastic cervical cytology and normal colposcopy" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

ROSE S, LETTERIE GERARD S, MIYAZAWA KUNIO: "Pregnancy rates using oil-based and water-based contrast medium in the evaluation of tubal patency" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

DEPARTMENT OF PATHOLOGY AND AREA LABORATORY SERVICES

DELAPLAIN CALVIN B, HILL MARVIN E, KINCAID STUART B, GAYLE EVERETT L, STINSON LAWRENCE W: "Mammographic appearance following injection mammoplasty: benign or malignant?"/Radiology

LEE MARGARET Y-T, STAPLETON LUKE M, WOODS JOSEPH C, CHO JOHN M: "Primary non-Hodgkin's lymphoma of the spleen: a case report"/Contemporary Surgery

PITCHER J DAVID, FLEET KATHLEEN, ROMASH MICHAEL M: "Titanium staining following total hip arthroplasty"/HI (21May88); Hi Ortho Asso 3rd combined spring symposium

SEAL LAWTON A, JAMISON RICHARD M: "A structural model for the genome of echovirus 22"/J Virol

UPHOUSE WILLIAM J, MARTIN RUSSELL R, LEE MARGARET Y-T, RONQUILLO AIDA P, COOPER GARY L, MCCORMACK DANIEL R: "Rapid remission of a large pleomorphic rhabdomyosarcoma with radiation and a novel schedule of simultaneous high dose cisplatin"/Cancer

WASSERMAN GLENN M, FAJARDO J EDUARDO, BASS JAMES W, COOK BRUCE A, BROOKS VIOLA B: "Tropical splenomegaly syndrome associated with cytomegalovirus infection"/Milit Med

ZACHARIAH ELIZABETH P, HOLMES SM, PEARSON JACK T: "Cerebral venous mycotic aneurysm: a case report"/J Neurosurg

DEPARTMENT OF PEDIATRICS

BASS JAMES W, PALMER STEPHEN R, MANDOJANA RICARDO, WITTLER ROBERT R: "Tinea nigra palmaris and plantaris: A black fungus producing black spots on the palms and soles"/Pediatr Infect Dis

PARSONS MARK K, MOREAU GORDON A, BOUCEK ROBERT Jr, GRAHAM THOMAS P Jr: "Acute shift of right ventricular distensibility after balloon pulmonary valvuloplasty"/Washington DC (14-17Nov88); Am Heart Asso Scientific Session

PARSONS MARK K, MOREAU GORDON A, GRAHAM THOMAS P Jr: "Echocardiographic determination of critical left ventricular size infants with isolated aortic valve stenosis"/*Washington, DC (14-17Nov88), Am Heart Asso Scientific Session;

RASZKA WILLIAM V JR, SMITH FRANKLIN R: "Penile torsion"/Am J Dis Child

RASZKA WILLIAM V, SMITH FRANKLIN R: "Superior vena cava in infants"/Clin Pediatr

WASSERMAN GLENN M, FAJARDO J EDUARDO, BASS JAMES W, COOK BRUCE A, BROOKS VIOLA B: "Tropical splenomegaly syndrome associated with cytomegalovirus infection"/Milit Med

PHYSICAL MEDICINE SERVICE

URIBE JOHN W, BENDOWSKI THOMAS F, HORTON RAMONA: "Arthroscopic subacromial decompression: short-term followup in 14 patients"/HI (21May88); Hi Ortho Asso 3rd combined spring symposium

DEPARTMENT OF PSYCHIATRY

ARMSTRONG SCOTT C: "Characteristics associated with psychiatric readmissions in active duty patients"/Hospital and Community Psychiatry

ARMSTRONG SCOTT C, ZEFF KARL N, FOLEN RAYMOND A: "Characteristics that effect outcome of psychiatrically hospitalized active duty patients"/Topeka, KS (11-15Apr88); Armed Forces Military Psychiatry Course

TOOK KEVIN J: "Thoughts on the clinical usefulness of similarities in the mental status examination"/Hosp Community Psychiatry

WEISS DAVID S: "A review of psychopharmacologic treatments for attention deficit disorder"/Pediatrics

ZEFF KARL N, CRANDELL EDWARD O, FOLEN RAYMOND A: "Characteristics associated with psychiatric readmissions in active duty patients"/Hospital and Community Psychiatry

ZEFF KARL: "Psychiatric side effects of haloperidol in the treatment of Tourette's Disorder"/The Jefferson J of Psych

DEPARTMENT OF RADIOLOGY

COUGHLIN WILLIAM F, McMURDO S KEITH: "Utility of CT in diagnosing spondylolysis of the axis vertebra"/Neuroradiology

COUGHLIN WILLIAM F, WILSON JAMES L, HAGGERTY MICHAEL F: "A post-appendectomy fecolith detected by ultrasound"/J Clinical Ultrasound

DELAPLAIN CALVIN B, HILL MARVIN E, KINCAID STUART B, GAYLE EVERETT L, STINSON LAWRENCE W: "Mammographic appearance following injection mammoplasty: benign or malignant?"/Radiology

DELAPLAIN CALVIN B, LING MICHAEL CC, YEH FRANCES, WASNICH RICHARD D: "Sequential dose injections: a new technique for Tc-99m colloid GI bleeding studies"/Clin Nucl Med

GRAHAM JON F: "Brain tumor metabolism and positron emission tomography"/chapter in book (this manuscript started while on active duty here at TAMC - MD presently in USAR)

JOHNSON FRED, COUGHLIN WILLIAM F: "The sensitivity of plain films in detecting appendiceal perforation in children"/Radiology

KOPELMAN JEROME N, WALTON DAVID, WILSON JAMES, MIYAZAWA KUNIO: "Antepartum diagnosis of arthrogryposis associated with trisomy 18" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

LETTERIE GERARD S, WILSON JAMES, MIYAZAWA KUNIO: "Magnetic resonance imaging of mullerian tract abnormalities"/Fertil Steril

SHIELS WILLIAM E: "Sonographic localization of soft tissue foreign bodies: diagnostic and therapeutic implications"/ (27Nov-2Dec88); 74th scientific assembly of the Radio So of North Am

SHIELS WILLIAM E, JOHNSON JF, STEPHENSON SR, HUANG YUAN-CHAO: "Chronic torsion of the wandering spleen"/Pediatr Radiol

UPHOUSE WILLIAM J, MARTIN RUSSELL R, LEE MARGARET Y-T, RONQUILLO AIDA P, COOPER GARY L, MCCORMACK DANIEL R: "Rapid remission of a large pleomorphic rhabdomyosarcoma with radiation and a novel schedule of simultaneous high dose cisplatin"/Cancer

ZACHARIAH ELIZABETH P, HOLMES SM, PEARSON JACK T: "Cerebral venous mycotic aneurysm: a case report"/J Neurosurg

DEPARTMENT OF SURGERY

CARDIOTHORACIC SURGERY SERVICE

JONES GARY P, WATTS DAVID M, BOWMAN GREG A, OLSEN JOHN D: "Giant benign mesothelioma"/Chest

GENERAL SURGERY SERVICE

BARCIA PETER J, GUSZ JOHN R: "Needle localized breast biopsy: finding the wire"/Surg Gynecol Obstet

COUGHLIN WILLIAM F, WILSON JAMES L, HAGGERTY MICHAEL F: "A post-appendectomy fecalith detected by ultrasound"/J Clinical Ultrasound

DELAPLAIN CALVIN B, HILL MARVIN E, KINCAID STUART B, GAYLE EVERETT L, STINSON LAWRENCE W: "Mammographic appearance following injection mammoplasty: benign or malignant?"/Radiology

FENGLER SCOTT A, BERENBERG JEFFREY L, LEE MARGARET Y-T: "Disseminated coagulopathies and advanced malignancies"/Cancer

JONES GARY P, WATTS DAVID M, BOWMAN GREG A, OLSEN JOHN D: "Giant benign mesothelioma"/Chest

LEE MARGARET Y-T: "Loco-Regional primary and recurrent melanoma: III. Update of natural history and non-systemic treatments (1980-1987)"/Cancer Treat Rev

LEE MARGARET Y-T: "Primary liver cancer: curative and palliative managements"/Current Hepatology

LEE MARGARET Y-T, LISEHORA GEORGE E: "Tuberculous peritonitis in a military hospital"/Surg Gynecol Obstet

LESHER SUSAN D, LEE MARGARET Y-T: "Acute pancreatitis in a military hospital"/Surg Gynecol Obstet

SHIELS WILLIAM E, JOHNSON JF, STEPHENSON SR, HUANG YUAN-CHAO: "Chronic torsion of the wandering spleen"/Pediatr Radiol

UPHOUSE WILLIAM J, MARTIN RUSSELL R, LEE MARGARET Y-T, RONQUILLO AIDA P, COOPER GARY L, MCCORMACK DANIEL R: "Rapid remission of a large pleomorphic rhabdomyosarcoma with radiation and a novel schedule of simultaneous high dose cisplatin"/Cancer

NEUROSURGERY

RATERINK MARK H, SOULIERE CHARLES S, SPETKA LAWRENCE: "Nasal dorsal sinus"/Washington DC (25-29Sep88); Am Acad of Oto - Head and Neck Surgery

ORTHOPEDIC SERVICE

BENDOWSKI THOMAS F, URIBE JOHN W: "Arthroscopic subacromial decompression: Short term followup in fourteen patients"/Williamsburg VA (5-9Dec88); Soc of Milit Ortho Surgeons/Orthopaedic Transactions

BENDOWSKI TF: "Arthroscopic Subacromial Decompression": Short Term Followup in Fourteen Patients. Mawaii Orthopaedic Association Third Annual Combined Spring Symposium, Kahuku, Hawaii, 21 May 1988.

BURCH REED A, JONES DONALD A: "Tibial talar fusion"/HI (21May88); Hi Ortho Asso 3rd combined spring symposium

BURCH RA: "Tibio-Talar Fusion"; 29th Annual Meeting of Society of Military Orthopaedic Surgeons (SOMOS), San Diego, California, 19 November 1987.

BURCH RA: "Tibial Talar Fusion". Hawaii Orthopaedic Association Third Annual Combined Spring Symposium, Kahuku, Hawaii, 21 May 1988.

FAY MJ: "Management of Acute Ankle Injuries". Second Aloha Conference of Physicians' Assistants, Honolulu, Hawaii, 27 September 1988.

FAY MJ: "Running Injuries". Second Aloha Conference of Physicians' Assistants, Honolulu, Mawaii, 27 September 1988.

FUGATE DOUGLAS S, ROMASH MICHAEL M: "Carcinoma cuniculatum (verrucous carcinoma) of the foot"/Foot Ankle

HYNES RICHARD A, JONES DONALD A: "Primary idiopathic lumbosacral scoliosis"/San Diego, CA (16-20Nov87); Soc of Military Ortho Surgeons

HYNES RICHARD A: "Percutaneous tendo-achilles repair: A ten-year review of the MA technique"/Williamsburg VA (5-9Dec88; Soc of Milit Ortho Surgeons

HYNES RA, JONES DA: "Primary Idiopathic Lumbosacral Scoliosis", 1988 Pediatric Orthopaedic Society of North America, Colorado Springs, Colorado, 5-8 May 1988.

HYNES RA, ROMASH MM: "Bilateral Symmetrical Synchronosis of Navicular First Cuneiform - Presenting as Lytic Lesion on X-ray". Foot and Ankle Journal, Vol 8, NO 3. December 1987.

HYNES RA: "Primary Idiopathic Lumbosacral Scoliosis"; 1988 American Orthopaedic Association Residents' Confefence at the Royal Sonesta Motel in Cambridge, Massachusetts on March 16-19, 1988.

MELICK LARRY B, REESOR KENNETH C: "Spiral tibial fractures of childhood"/Emergency Medicine

MELICK LB, REINKER KA, REESOR KE: "Tibial Fractures of Young Children, Pediatric Emergency Care", (accepted for publication per letter of 12 October 1987).

PARKINSON DW, MITSUNAGA M, JONES DA: "Arthrodesis of the Paralytic Shoulder in Children". 29th Annual Meeting Of the Society of Military Orthopaedic Surgeons, San Diego, California, 16 - 20 November 1987.

PITCHER J DAVID JR, ROMASH MICHAEL M: "Displaced femoral stress fractures: a retrospective study of their prevalence"/*(Apr88) ann mtg of Am Fracture Asso; Orthopaedic Transactions

PITCHER J DAVID, FLEET KATHLEEN, ROMASH MICHAEL M: "Titanium staining following total hip arthroplasty"/HI (21May88); Hi Ortho Asso 3rd combined spring symposium

PITCHER JD: "Titanium Staining Following Total Hip Arthroplasty". Hawaii Orthopaedic Association Third Annual Combined Spring Symposium, Kahuku, Hawaii, 21 May 1988.

QUINLAN ED: "Commonly Missed Diagnoses in Orthopaedic Trauma". Second Aloha Conference of Physicians' Assistants, Honolulu, Hawaii, 27 September 1988.

REESOR KENNETH E, REINKER KENT A: "Limb lengthening without bone graft of internal fixation"; Hawaii Orthopaedic Association Third Annual Combined Spring Symposium, Kahuku, Hawaii, 21 May 1988.

REINKER KENT A, GARDNER RICHARD: "Scleroderma in children"/Colorado Springs, CO (5-8May88); Ann mtg of Pediatric Ortho Soc of North Am

REINKER KENT A, JONES RON C: "Vertebral infections: A clinical review"/Williamsburg VA (5-9Dec88); Soc of Milit Ortho Surgeons

REINKER KENT A: "Complications in the treatment of congenital dislocation of the hip"/Aurora, CO (9-11Mar88); 16th ann symposium of Children's Orthopaedics

REINKER KENT A: "Osteomyelitis - an update for 1987"/(spring issue) Orthopod

REINKER KA, DAVIS JS: "Blount's Disease - A Reappraisal", Pediatric Orthopaedics (submitted for publication 1986).

REINKER KA: "Osteomyelitis"; Sixtieth Annual Clinical Assembly of Osteopathic Specialists, Sheraton Waikiki Hotel, Honolulu, Hawaii, 21 October 1987.

REINKER KA: Biomechanics Symposium, Dwight D. Eisenhower Army Medical Center, Fort Gordon, Georgia, 28-29 April 1988.

ROMASH MICHAEL M, HENNINGSEN HAROLD J, CLAYBAUGH JOHN R: "Knee braces - comparative functional testing"/J Bone Joint Surg

ROMASH MICHAEL M.: "Theories of Wound and Collagen Healing", Sixtieth Annual Clinical Assembly of Osteopathic Specialists, 21 Oct 1987, Sheraton Waikiki Hotel, Honolulu, Hawaii.

ROMASH MICHAEL M: "The removeable rigid post-op dressing and pylon for BKA: Rehab without a prosthetist"/San Diego, CA (16-20Nov87)

ROMASH MM: "Calcaneal Fractures - Three Dimensional Treatment". Foot and Ankle, Vol 8, No 4, February 1988.

SCHMIDT DAVID M, MITSUNAGA MORRIS M: "Proximal femoral varus osteotomy and the spastic dislocating hip"/HI (21May88); Hi Ortho Asso 3rd combined spring symposium/J Pediatr Orthop

SCHMIDT DM, ROMASH MM: "Atraumatic Vascular Necrosis of the Head of the Talus: A Case Report". Foot and Ankle, Vol 8, No 4, February 1988.

TIPPETS DUANE D, MITSUNAGA M, JONES DE: "The surgical treatment of leg length inequality"/Orthopaedic transactions/Hi Ortho Asso 3rd combined spring symposium

TIPPETS DUANE D, URIBE JOHN W, COLLINS ROGER B, BURCH REED A: "The impact of technological advances and more stringent performance standards on orthopaedic surgery in the military"/Milit Med

TIPPETS DD: "Surgical Treatment of Leg Length Inequality". Hawaii Orthopaedic Association Third Annual Spring Symposium, Kahuku, Hawaii, 21 May 1988.

TIPPETS DD, MITSUNAGA M, Jones DA: "Surgical Treatment of Leg Length Inequality". 55th Annual Meeting of the American Academy of Orthopaedic Surgeons, Atlanta, Georgia, 6 February 1988.

TIPPETS DD, MITSUNAGA MM, JONES DE: "The Surgical Treatment of Leg Length Inequality". Orthopaedic Transactions, (submitted for publication).

URIBE JOHN W, BENDOWSKI THOMAS F, HORTON RAMONA: "Arthroscopic subacromial decompression: short-term followup in 14 patients"/HI (21May88); Hi Ortho Asso 3rd combined spring symposium

WEST GREGORY G, ROMASH MICHAEL M, MITSUNAGA MM: "Analysis of calcar resorption in collared low-modulus titanium femoral components"/* HI (21May88), Hi Ortho Asso 3rd combined spring symposium; Orthopaedic transactions

WEST GREGORY G, ROMASH MICHAEL M, MITSUNAGA MORRIS M: "Analysis of calcar resorption in collared low modulus titanium alloy femoral components"/Honolulu, HI (29Jan88) - Pan-Pacific Surgical Asso Mtg & Atlanta, GA (6Feb88) - 55th ann mtg of Am Acad of Ortho Surgeons

WEST GG, ROMASH MM, MITSUNAGA MM: "Analysis of Calcar Resorption in Collared Low-Modulus Titanium Femoral Components", Orthopaedic Transactions, (submitted for publication 1988).

WEST GG, ROMASH MM, MITSUNAGA M; "Analysis of Calcar Resorption in Collared Low Modulus Titanium Alloy Femoral Components", 55th Annual Meeting of the American Academy of Orthopaedic Surgeons, Atlanta, Georgia, February 1988.

WEST GG: Analysis of Calcar Resorption in Collared Low Modulus Titanium Femoral Components. Hawaii Orthopaedic Association Third Annual Spring Symposium, Kahuku, Hawaii, 21 May 1988.

WEST GG, Romash MM, Mitsunaga MM: "Analysis of Calcar Resorption in Collared Low-modulus Titanium Total Hip Components". 19th Biennial Surgical Congress of the Pan-Pacific Surgical Association, Honolulu, Hawaii, 29 January 1988.

YANKLOWITZ BARNEY A: "Cystic subcutaneous eumycetoma of the foot"/Ft Carson, CO (5- 7Apr88); US Army Podiatry Conf

YANKLOWITZ BARNEY A: "Cystic subcutaneous eumycetoma of the foot"/J Am Podiatr Med Assoc

YANKLOWITZ B.: "Common Foot Conditions". Second Aloha Conference of Physicians' Assistants, Honolulu, Hawaii, 27 September 1988.

OTOLARYNGOLOGY SERVICE

LETTERIE GERARD S, VAUSS-STAPLETON NL, MIYAZAWA KUNIO: "Mullerian tract abnormalities and associated auditory deficiencies" abstract/San Antonio TX (6-10Nov88); Armed Forces ACOG Mtg

MARTIN MICHAEL: "Pharyngeal space pleomorphic adenoma"/Washington DC (22-29Sep88); Am Acad of Oto - Head & Neck Surgery

PARK ALFRED O, ANTOINE GREGORY A: "Squamous cell carcinoma of the thyroid"/Arch Otolaryngol

RATERINK MARK H: "Median nasal fistula and cyst" poster/Washington DC (25-29Sep88); Am Acad of Oto - Head & Neck Surgery

RATERINK MARK H, SOULIERE CHARLES S, SPETKA LAWRENCE: "Nasal dorsal sinus"/Washington DC (25-29Sep88); Am Acad of Oto - Head and Neck Surgery

SOULIERE CHARLES R, ANTOINE GREGORY A, MARTIN MICHAEL P, BLUMBERG ANDREY I, ISAACSON GLENN C: "Medical versus surgical therapy for subperiosteal abscess of the orbit"/Coronado, CA (25-29Jun88); 72nd ann Pacific Oto-Ophth Soc Mtg

VAUSE-STAPLETON NL: "HEARS - the Army's automated data registry for hearing conservation"/ Breckenridge, CO (5-12Mar88); Colorado Hearing Foundation, 22nd CO Oto-Audio wkshp

YIM DONALD W S: The external combination rhinoplasty approach access for management of the problem nasal deformity"/ Honolulu, HI (7Dec87); "Advances for Oto" seminar sponsored by Manhattan EE&T Hospital

YIM DONALD WS, ZIESKE LARRY A: "Open rhinoplasty approach for transseptal sphenoid sinus and transsphenoidal surgery"/Washington DC (22-29Sep88); combined ann mtg of Am Acad of Facial Plastic and Reconstructive Surgery and Am Acad of Oto - Head & Neck Surgery

ZIESKE LARRY A, JOHNSON JONAS T, MYERS EUGENE N, SCHRAMM VICTOR L, WAGNER ROBIN: "Composite resection reconstructional: split-thickness skin graft-A preferred option"/Honolulu, HI (7-8Dec87); "Advances for Oto" seminar sponsored by Manhattan EE& T Hospital

ZIESKE LARRY A, MARTIN MICHAEL C: "Parapharyngeal space pleomorphic adenoma"/Washington DC (22-29Sep88); Am Acad of Oto - Head & Neck Surgery

PLASTIC SURGERY SERVICE

DELAPLAIN CALVIN B, HILL MARVIN E, KINCAID STUART B, GAYLE EVERETT L, STINSON LAWRENCE W: "Mammographic appearance following injection mammoplasty: benign or malignant?"/Radiology

UROLOGY SERVICE

DESMOND PM, KREDER KJ, DRESNER ML: A Case of Penile Carcinoma in a Circumcised Male, proceedings of the Kimbrough Urologic Seminar, Washington, D.C., Nov 1987.

DRESNER ML: Cryptorchidism. American College of Osteopathic Meeting, Honolulu, Hawaii, Oct 1987.

DRESNER ML, SATERI F, KREDER KJ, SHAVVER TR, HUANG YC: Urachal Extrophy, presented at the Kimbrough Urologic Seminar, Washington, D.C., Nov 1987.

KENNON WG: Advances in the Diagnosis of Hematuria. American College of Osteopathic Meeting, Honolulu, Hawaii, Oct 1987.

KENNON WG: Diphosphonate Therapy for Metastatic Prostate Cancer. Kimbrough Urologic Seminar, Washington, D.C., Nov 1987.

KREDER KJ, DRESNER ML: Testicular Tumors of Childhood, presented at the American College of Osteopathic Surgeons Meeting, Honolulu, Hawaii, Oct 1987.

KREDER KJ, DRESNER ML: The XX Male Syndrome, proceedings of the Kimbrough Urologic Seminar, Washington, D.C., Nov 1987. Presented at Chief Residents Conference, Newport, Rhode Island, May 1988.

KREDER KARL J, KENNON WILLIAM G, DRESNER MARTIN L: "A massive pediatric testis tumor"/J Urol

MOREY ALLEN F, KREDER KARL J, WIKERT GARY P, COOPER GARY, DRESNER MARTIN L: "Ectopic prostate tissue at the bladder dome"/J Urol

PLISKIN MJ: Renal Cell Carcinoma in a Cadaver Donor Kidney. American College of Osteopathic Meeting, Honolulu, Hawaii, Oct 1987. Accepted by Urology, Feb 1987.

PLISKIN MJ: Inadvertent Urethral Insertion of a Contraceptive Suppository. Presented at Kimbrough Urologic Seminar, Washington, D.C., Nov 1987. J. Urology, 139:1049-1050, May 1988.

PLISKIN MARC J, KREDER KARL J, DESMOND PAUL M, DRESNER MARTIN L: "Cocaine and lidocaine as topical urethral anesthetics"/American College of Osteopathic Meeting, Honolulu, Hawaii, Oct 1987./J Urol

WIKERT GARY A, KREDER KARL J, DRESNER MARTIN L: "Extracorporeal shock wave lithotripsy and adult polycystic kidney disease"/ Proceedings of the Kimbrough Urologic Seminar, Washington, D.C., Nov 1987./ J Urol

PREVENTIVE MEDICINE SERVICE

BOUDREAU EF, PANG LW, CHAIKUMMAO S, WITAYRAUT C, THIEMANUN W, POOKASORN M: "Comparison of Mefloquine, Chloroquine Plus "Fansidar" and Chloroquine Alone as Malarial Prophylaxis in Eastern Thailand". (Manuscript in preparation)

BOUDREAU EF, PANG LW, DIXON KE, WEBSTER HK, PAVANAND K, TOSINGHA L, SOMUTSAKORN P, CANFIELD C: "Treatment Efficacy of Halofantrine (WR 171,669) in Initial Field Trials in Thailand". Bull. of WHO, 66 (2): 227-35, 1988.

HARBACH RE, GINGRICH JB, PANG LW: "Some Entomological Observations on Malaria Transmission in a Remote Village in Northwestern Thailand", Journal of the American Mosquito Control Assn, Vol. 3, No. 2, June 1987, p. 296-301.

LIMSOMWONG N, PANG LW, SINGHARAJ P: "Malaria Prophylaxis with Proguanil in Children Living in a Malaria Endemic Area". American J. Trop. Med. Hyg., 38(2): 231-36, 1988.

PANG LW, LIMSOMWONG N, BOUDREAU EF, SINGHARAJ P: "Doxycycline Prophylaxis for Falciparum Malaria". The Lancet, May 23, 1987, p. 1161-1164.

PANG LW, LIMSOMWONG N, SINGHARAJ P, CANFIELD CJ: "Malaria prophylaxis with proguanil and sulfisoxazole in children living in a malaria endemic area". Accepted as a WHOMAL publication and in press Bull of WHO.

PANG LW, LIMSOMWONG N, SINGHARAJ P: "Falciparum and Vivax Malaria prophylaxis with Low Dose Doxycycline". (In press JID, Nov 1988)

PANG LW, LIMSONWONG N, WEBSTER HK, KARWACKI JJ: "Circumsporozoite Antibodies and Falciparum Malaria Incidence in Children Living in a Malaria Endemic Area". Bull. of WHO 66(3): 359-63, 1988.

PANG LW: "Doxycycline Prophylaxis for Malaria" - Letter Lancet, 1987, 2:970.
CHILDS GE, PANG LW: "Analysis of dose-response curves for the in vitro susceptibility of Plasmodium falciparum to antimalarials using a pocket computer". American J Trop Med Hyg; 38:15-18, 1988.

WEBSTER HK, BOUDREAU EF, PANG LW, PERMPANICH B, SOOKTO P., WIRTZ RA: "Development of Immunity in Natural Plasmodium falciparum Malaria: Antibodies to the Falciparum Sporozoite Vaccine 1 Antigen (R32tet32)", Journal of Clinical Microbiology, June 1987, p. 1002-1008.

USADENTAC HAWAII

BAUMAN R, KRAUT R, SKIRVIN D, MCCARTNEY J, KUJAR K, MAHAFFEY J: "Osseo-integrated Implants - a Status Report" to the Leeward Prosthodontic Society, Honolulu, Hawaii, 26 April 1988.

BAUMAN R: "Rotational Path Partial Dentures" to the Leeward Prosthodontic Society, Honolulu, Hawaii, 28 June 1988.

HARVEY KESSLER: "AIDS and Educational Strategies for AIDS in the Dental Setting" at the Workshop for the Hawaii State Dept of Health Educational Symposium on AIDS, Honolulu, Hawaii.

KESSLER H, DALEY C: "Forensic Dentistry", Annual Meeting of the Pacific Dental and Hawaii Dental Society in Honolulu, Hawaii 21 January 1987.

KESSLER H: "AIDS Update" to the Leeward Prosthodontic Society, Honolulu, Hawaii, 26 July 1988.

KESSLER H: "AIDS and Hepatitis" to Kona-Kailua Dental Health Care Workers, Kona, Hawaii, 5 December, 1987.

KESSLER H: "Radiographic Anatomy, Radiographic Pitfalls and Radiographic Pathology" at Dental Seminars and Symposia, Maui, Hawaii, 1 February 1988.

KRAUT R, KUJAR K: "Hydroxyapatite-Coated Dental Implants Used for the Treatment of Edentulous Mandibles" IN Compendium of Continuing Education. May 1988.

KRAUT R: "Comparison of the Physiologic Effects of Enflurane and Isoflurane for Outpatient General Anesthesia", Anesthesia Progress Vol 35. No.1 Jan/Feb 1988 pp5-8.

KRAUT R: "Future Applications of Dental Implants", Annual Meeting of the Pacific Dental and Hawaii Dental Society in Honolulu, Hawaii 21 January 1987.

Detail Summary Sheet

Prot No: 51H85	Status: Terminated
TITLE: Altitude Sickness in Soldiers at 4200 Meters (Mauna Kea IV)	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Y. C. Lin, Ph.D.; CPT B. J. Freund, MC	
Department/Section: Clinical Investigation/Physiology	
Key Words: high altitude; exercise; mineralocorticoid supplementation; acetazolamide therapy; lung water; water and electrolyte balance; ophthalmology	
Funding: FY 87: NA FY 88: NA	Periodic Review Date: Sep 88
Gifts: USAMRDC grant requested	Decision: Terminate

OBJECTIVE: (1) Does exercise increase the vulnerability to acute mountain sickness (AMS) and complications? (2) Does acetazolamide (AZ) decrease the vulnerability of exercising soldiers to AMS at altitude? (3) Does AZ protect soldiers from exercise-induced fluid accumulation in the lung at high altitude? (4) Does AZ affect the hormonal responses to exercise and the 24-hour hormonal and water and electrolyte parameters? (5) Does the normally occurring decrease in aldosterone at high altitude have an effect on the occurrence of AMS, accumulation of lung water, and water and electrolyte balances? (6) Does high altitude exposure with no treatment differ from AZ or mineralocorticoid-treated subjects in ophthalmic measurements?

TECHNICAL APPROACH: Twenty-four subjects will be divided into three groups: group 1 = no treatment, group 2 = AZ pretreatment, group 3 = mineralocorticoid treatment. All subjects will run two hours per day at 4,100 M for 7 consecutive days. Twenty-four-hour urine will be collected throughout, as well as occasional pre- and postexercise blood samples.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No subjects were enrolled.

In order to conduct this study outside funding is essential. We requested USMRDC funding in 1985, but we were informed that they had no more money available for high altitude research that year, probably due to the OE2 study at USARIEM. In 1987 our department experienced a turnover in almost all personnel, and the loss of two MSC research slots and the graduation of two highly experienced Ph.D. students. This proposal will not be submitted in its present form for funding, so we will rewrite a new proposal.

Detail Summary Sheet

Prot No: 26A86	Status: Completed
TITLE: The Effect of Acetazolamide on Plasma and Cerebrospinal Fluid Antidiuretic Hormone (ADH) Concentrations in Conscious Goats During Acute Exposure to Simulated High Altitude	
Principal Investigator: Dr. John R. Claybaugh, Ph.D.	
Associate Investigators: CPT Beau J. Freund; Aileen K. Sato	
Department/Section: Clinical Investigation/Veterinary	
Key Words: high altitude; ADH; acetazolamide	
Funding: FY 87: NA	FY 88: NA
Gifts: None	Periodic Review Date: Sep 88
	Decision: Completed

OBJECTIVE: To establish a conscious goat model for studying the effects of simulated high altitude hypoxia and to determine if the drug, acetazolamide, is effective in preventing the increased concentrations of ADH observed in cerebrospinal fluid as a result of acute exposure to simulated high altitude.

TECHNICAL APPROACH: Six adult female goats will be surgically prepared with a chronic tracheostomy, exteriorized carotid loop, and chronic implantation of a stainless steel guide tube over the cisterna magna. The goats will then be allowed to recover for at least four weeks after surgery. Each goat will undergo four experiments: (1) normoxia (sea level), (2) normoxia with ACZ pretreatment, (3) hypoxia (simulated high altitude), and (4) hypoxia with ACZ pretreatment. ACZ pretreatment will consist of 250 mg ACZ given orally b.i.d. for 72 hours prior to hypoxia/normoxia. Hypoxic gases will be administered via a cuffed tracheostomy tube. CSF, plasma, and urine samples are analyzed for arginine vasopressin, osmolality, electrolytes, and other hormones and other measurements including blood pressure, blood gases, and respiratory parameters.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Three goats successfully completed all four protocols. The results indicate that the plasma vasopressin response to hypoxia is transient. That is, during the six hours of continuous exposure to have 7% O₂, plasma vasopressin concentration was significantly elevated during the first and second hours and then returned to baseline despite continued hypoxia and similar blood gas profiles. Acetazolamide had no effect on the response. CSF concentrations of vasopressin were only elevated during the second hour 7% O₂ without acetazolamide treatment experiments, but were not significantly different from the other experimental protocols. Results have been published in the abstracts for the 71st FASEB meetings, Washington, D.C., 1987.

Detail Summary Sheet

Prot No: 41A86	Status: Ongoing
TITLE: Effects of Elevated Mineralocorticoid on Blood Pressure, Thirst, and Vasopressin Responses to Angiotensin in the Goat	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: CPT Beau J. Freund, MS	
Department/Section: Clinical Investigation/Physiology	
Key Words: mineralocorticoid; vasopressin; angiotensin	
Funding: FY 87: NA	FY 88: \$16,128
Gifts: VA/DOD Grant Pending	Periodic Review Date: Sep 88
	Decision: Continue

OBJECTIVE: To determine if the vasopressin (VP) response to angiotensin II is enhanced by previous administration of aldosterone, and whether the VP responses to central or peripheral administration of angiotensin II are differentially affected by the aldosterone treatment.

TECHNICAL APPROACH: Goats will be surgically prepared with chronic and indwelling cannula in the lateral ventricle of the brain and a carotid arterial loop. After two weeks of aldosterone or vehicle injections, the responsiveness to angiotensin II will be determined. The angiotensin will be administered IV or into the lateral ventricle of the brain. The blood pressure, thirst, and CSF and plasma ADH responses will be determined.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Progress: Prior administration of mineralocorticoid (DOCA), as expected reduces resting levels of plasma renin activity (PRA). We also observed a significant increase in atrial natriuretic factor (ANF). Peripheral iv administration of angiotensin II (n=6) significantly reduced PRA, and increased ANF, vasopressin, and blood pressure in goats with and without prior DOCA administration. DOCA administration only affected the vasopressin response to iv angiotensin II. Vasopressin stimulation was reduced compared to no DOCA administration. Intracerebroventricular angiotensin II stimulated vasopressin and thirst, and increased blood pressure (n=3), but no differences in these responses appears to be affected by prior administration of DOCA. Samples have been set aside for ACTH analysis, and more experiments must be conducted. However, contrary to some previous reports, prior DOCA administration does not appear to "up-regulate" angiotensin II receptors in the present experimental design.

Detail Summary Sheet

Prot No: 1A88	Status: Ongoing
TITLE: Effects of des-leu angiotensin I, cortisol, and hyperbaria on the release of vasopressin from the isolated hypothalamoneurohypophyseal system	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Aileen K. Sato, Med. Tech, Glenn M. Hashiro, Biol. Lab Tech., CPT Beau J. Freund, MSC, David G. Changaris, MD, Suk Ki Hong, MD, Ph.D.	
Department/Section: Clinical Investigation	
Key Words: des-leu angiotensin I	
Funding: FY 87: NA	FY 88: \$6,243.
Gifts: None	Periodic Review Date: Nov 87 Decision: Continue

OBJECTIVE: 1) To determine if des-leu angiotensin I is able to stimulate vasopressin from the isolated hypothalamoneurohypophyseal system (HNS) in a manner similar to angiotensin II. 2) To determine if cortisol can inhibit baseline or stimulated vasopressin release from the HNS. 3) To determine if hyperbaria will inhibit the release of vasopressin from the HNS.

TECHNICAL APPROACH: Two approaches have been followed, a tissue incubation (acute) and a tissue culture (chronic) approach. Both involve the surgical removal of the floor of the brain of the rat, a triangular piece of tissue approximately 1 mm thick, with a base extending parallel and anterior to the optic chiasma, and the apex approximately 2 mm posterior to the stalk of the neurohypophysis. The anterior pituitary is removed. The resulting tissue block includes the supraoptic nucleus with intact axonal projections through the stalk to the neurohypophysis.

We have not begun technical approaches to the specific problems inherent to objectives 2 and 3.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The chronic preparation, although preferred, is still not functional. Emphasis has therefore been placed on the acute preparation. We have been able to stimulate vasopressin release with .00005 M angiotensin II, and with an osmotic stimulation of 400 mOsm/kg H₂O in the media, and with 56 mM KCl. des-leu Angiotensin II appears to be an order of magnitude less sensitive in the stimulation of vasopressin. So far approximately 20 preparations have been used in experiments.

Detail Summary Sheet

Prot No: 28A87	Status: Ongoing
TITLE: Mechanism of Cold Induced Diuresis: a Pilot Protocol	
Principal Investigator: Margaret S. Dice, Biological Laboratory Technician	
Associate Investigators: John R. Claybaugh, Ph.D.; Aileen K. Sato; CPT Beau J. Freund, MS	
Department/Section: Clinical Investigation/Physiology	
Key Words: cold diuresis	
Funding: FY 87: NA	FY 88: \$5,813.
Gifts: *NIH#HL28542	Periodic Review Date: Jun 88 Decision: Continue

OBJECTIVE: This is a pilot protocol to develop the rat as a model for studying hormonal determinants of cold diuresis.

TECHNICAL APPROACH: To evaluate the diuretic response of conscious rats to low ambient temperatures - blood pressure, relevant blood and urinary hormones, and urine flows will be measured via indwelling catheters. Consequently, the development of methods for surgically implanting and maintaining bladder, and femoral arterial and venous catheters is the primary technical focus of this pilot.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Nineteen animals have been surgerized to date. Surgical implantation of catheters has progressed to a satisfactory stage of ease and rapidity. Problems of catheter destruction by the animal have also been overcome.

*\$15,647. NIH grant support.

Detail Summary Sheet

Prot No: 35H87	Status: Completed
TITLE: Osmotic Control of Vasopressin Release in Endurance Trained and Untrained Men	
Principal Investigator: CPT Beau J. Freund, Ph.D.	
Associate Investigators: John R. Claybaugh, Ph.D.	
Department/Section: Clinical Investigation	
Key Words: plasma vasopressin; plasma osmolality	
Funding: FY 87: NA FY 88: \$1,623.	Periodic Review Date: Jul 88
Gifts: None	Decision: Completed

OBJECTIVE: The purpose of this study is to determine if chronic endurance exercise training alters the regulation of plasma vasopressin by examining the relationship of this hormone to changes in plasma osmolality.

TECHNICAL APPROACH: Seven endurance trained and 7 sedentary subjects will be infused with a 0.45% NaCl and/or a D5W (glucose) solution following 16 hours of dehydration. Blood pressure, plasma electrolytes, osmolality, and fluid regulating hormones including vasopressin, atrial natriuretic factor, aldosterone, and plasma renin activity will be measured at various time intervals. By altering plasma osmolality and then measuring the vasopressin response, the threshold and sensitivity of vasopressin to changes in osmolality can be assessed.

PROGRESS: No. of Subjects Enrolled - To Date: 12 Reporting Period: 12

All testing has been completed. Statistical analysis has been performed and an abstract from the collected data has been presented and published. (Federation of American Societies for Experimental Biology in Las Vegas, March 1988, published in the FASEB Journal 2: A1484, 1988). An additional manuscript is currently being worked on and will be submitted to the Journal of Applied Physiology when completed.

Adverse Effects: Two subjects both in the highly trained group experienced various degrees of a "vaso vagal" response to the catheter insertion. This included mild degrees of nausea, dizziness, and sweating. The subjects were placed in a supine position with feet elevated and recovered in a short period of time. No other adverse effects were noted and all subjects completed the study.

Manuscript in preparation.

Detail Summary Sheet

Prot No: 4A88	Status: Ongoing
TITLE: Are the Natriuretic and Diuretic Actions of Atrial Natriuretic Factor Dopamine Dependent?	
Principal Investigator: CPT Beau J. Freund, Ph.D., MSC	
Associate Investigators: John R. Claybaugh, Ph.D., MAJ Albert H. McCullen, VC,	
Department/Section: Clinical Investigation	
Key Words: atrial natriuretic factor (ANF)	
Funding: FY 87: NA	FY 88: \$877.
Gifts: None	Periodic Review Date: Nov 87
	Decision: Continue

OBJECTIVE: 1) To document a diuresis and natriuresis during blood volume expansion with isotonic saline using the adult female goat as the experimental model. 2) To determine the response of atrial natriuretic factor (ANF) and dopamine to saline infusion. 3) To determine if a dopamine antagonist (Haloperidol or Domperidone) can blunt the infusion induced diuresis or natriuresis. 4) To determine any interactive effects of other fluid regulating hormones, i.e., plasma renin activity, aldosterone, or antidiuretic hormone.

TECHNICAL APPROACH: Ten female goats will be surgically prepared with an exteriorized carotid loop. Following recovery from surgery (minimum 2 weeks) experimental procedures to include bladder catheterization and blood volume expansion via saline infusion will occur both with and without dopamine blockade with halperidol. Renal and hormonal responses will be evaluated and statistically compared between the dopamine antagonist and control conditions.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date 5 goats have been prepared with an exteriorized carotid loop. Experimental procedures and hormonal assays are scheduled to occur over the next year.

Detail Summary Sheet

Prot No: 39H88	Status: Ongoing
TITLE: Hormonal and Renal Responses to Exercise: Effects of Exercise Intensity	
Principal Investigator: CPT Beau J. Freund, MS	
Associate Investigators: Everett M. Shizuru, Graduate Student; John R. Claybaugh, Ph.D.; MAJ Thomas A. Perkins, MC Glenn Hashiro, M.S.	
Department/Section: Clinical Investigation	
Key Words: hormonal and renal responses;	
Funding: FY 87: NA	FY 88: \$1,512.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: The purpose of this study will be to: 1) investigate the effects of exercise intensity on renal function; 2) determine the mechanisms responsible for the diuresis and natriuresis reported during low intensity exercise; and 3) to investigate the stimuli responsible for the release of atrial natriuretic peptide (ANP).

TECHNICAL APPROACH: Subjects: Eight to twelve healthy male subjects of varying fitness states and between the ages of 20 and 39 years will be recruited for this study. The methodology and experimental protocol will be explained in detail to all prospective subjects with written informed consent being obtained prior to data collection. In addition, all subjects will be informed that they may withdraw at any time from the study without ill will.

PROGRESS: No. of Subjects Enrolled - To Date: 8 Reporting Period: 8

All testing and data collection has been completed on the 8 subjects enrolled. Statistical analysis is currently being performed and manuscript is to be written over the next year.

Adverse Effects: No adverse effects occurred in any of the subjects.

Detail Summary Sheet

Prot No: 6A88	Status: Ongoing
TITLE: The Ontogeny of Vasopressin Receptors in Vascular Smooth Muscle in the Guinea Pig	
Principal Investigator: Linda K. Kullama, Ph.D.	
Associate Investigators: John R. Claybaugh, Ph.D., Kenneth T. Nakamura, MD Dr. Venkataraman Balaraman, M.D.	
Department/Section: Clinical Investigation	
Key Words: arginine vasopressin (AVP); vascular smooth muscle responses	
Funding: FY 87: NA	FY 88: \$6,161.
Gifts: None	Periodic Review Date: Dec 87 Decision: Continue

OBJECTIVE: The objective of this study is to investigate the ontogeny of vascular smooth muscle responses to arginine vasopressin (AVP) using aortic ring segments from fetal, newborn, and adult guinea pigs. We will examine the AVP-mediated vasoconstriction, vasodilation, and the effect of endothelium dependent relaxing factor (EDRF) on modifying changes in isometric force.

TECHNICAL APPROACH: Isolated vascular rings are mounted in organ bath and bathed in Kreb's solution aerated continuously with 95%O₂, 5%CO₂. Isometric contractile responses are studied by addition of cumulative doses of drugs mediating vasoconstriction. The responses are recorded using a Grass .03 force displacement transducer attached to a Gould recording device. Thus dose response curves to the various vasoconstrictors are generated and differences compared using standard statistical tests.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Cumulative dose response curves to norepinephrine, vasopressin and vasotocin were generated in thoracic aortae of 1-3 day, 5-7 day and 12 week old Sprague-Dawley rats. Preliminary results include that: 1) the responses to Vasopressin, corrected for surface area and density show a progressive increase in the maximum force generated with increasing age and 2) the ratio of Vasotocin to Vasopressin response decreases significantly with age. The ontogeny of vascular responses to Vasopressin and Vasotocin have not been studied. At the conclusion of the present project, the physiologic functions of these hormones with respect to modulation of vascular responses during ontogeny can be better understood. To our knowledge, at present, these have not been studied.

No. of animals used: Sprague-Dawley Rats - 95.

Detail Summary Sheet

Prot No: 38A88

Status: Ongoing

TITLE: The Ontogeny of cGMP Mediated Relaxation in Smooth Muscle (e.g. aorta, pulmonary artery, trachea etc.,) of Developing Fetal, Newborn and Adult Guinea Pigs and Rats

Principal Investigator: Linda K. Kullama, Ph.D.

Associate Investigators: Dr. Venkataraman Balaraman, M.D.;
Dr. Kenneth T. Nakamura, M.D.;
John R. Claybaugh, Ph.D.

Department/Section: Clinical Investigation

Key Words: ontogeny;

Funding: FY 87: NA

FY 88: \$6,128.

Periodic Review Date: Jul 88

Gifts: None

Decision: Continue

OBJECTIVE: The objective of this study is to determine the ontogeny of cGMP mediated relaxation in smooth muscle (isolated vascular rings, tracheal rings etc.,) of developing fetal, newborn and adult guinea pigs and newborn and adult rats. We will use three different classes of pharmacological agents which stimulate cGMP by different mechanisms, viz., directly at the level of smooth muscle, receptor mediated release and endothelium dependent relaxing factor (EDRF) mediated release.

TECHNICAL APPROACH: Isolated smooth muscle structures (vascular rings, tracheal rings) are mounted in isolated organ bath and bathed in Kreb's solution aereated continuously with 95%O₂, 5%CO₂. Isometric relaxation responses are studied by addition of cumulative doses of drugs mediating relaxation after the tissue is precontracted with a known constricting agent. The responses are recorded using a Grass .03 force displacement transducer attached to a Gould recording device. Thus dose response curves to the various relaxing agents are generated and differences compared using standard statistical tests.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date, relaxation responses occurred in the thoracic aortate of (1) Fetal (55-60 day gestation, term begin 68 days), (2) Newborn (1-3 day old) and (3) Adult (12 weeks) Hartley guinea pigs to acetylcholine, sodium nitroprusside and atriopeptin III. Preliminary observations and analysis of our data indicates: (1) no difference in the ontogeny of relaxation responses to atriopeptin III, (2) relaxation responses to sodium nitroprusside show a progressive increase (shift of the dose response curve to the left) in responsiveness with increasing age; and (3) relaxation responses to acetylcholine show a progressive decrease (shift of the dose response curve to the right) in responsiveness with increasing age. The ontogeny of relaxation responses mediated by cGMP has not been studied. At the conclusion of the proposed studies and with knowledge of the ontogeny of relaxation responses, meaningful approaches to pharmacology of vasodilators in the perinatal period can be proposed. Total No. of animals used: 20.

Detail Summary Sheet

Prot No: 44A88	Status: Ongoing
TITLE: Pilot Study: Investigation of Transplanted Tumor Cell Lines in Mice: Establishment of Cancer Models at Tripler AMC to Support Research Protocols in Pathology, Surgery, and Medicine	
Principal Investigator: COL Kay Alvin Kyser, MC	
Associate Investigators: LTC Y-T. Margaret Lee, MC; CPT Kraig S. Lerud, MC; Dan Brooks, MT; Cindy Ollinger; Sgt Anne Brady	
Department/Section: Clinical Investigation	
Key Words: tumor cell lines;	
Funding: FY 87: NA	FY 88: \$2,425.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To establish experimental cancer models at Tripler to support training and research on naturally occurring and man-made antitumor substances.

TECHNICAL APPROACH: Transfer of technology from Letterman AMC to establish mouse tumor colony. Traditional line cancer transfer. Estrogen receptor quantification using computer enhanced microscopy.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA
Protocol not started due to shortage of funds.

Detail Summary Sheet

Prot No: 20A88	Status: Ongoing
TITLE: Stop-flow Analysis of Sodium Entry and Tubular Transit Times for Sodium and Inulin in Normal and Nephrotic Rats	
Principal Investigator: Dr. Ralph Keeler, Ph.D.	
Associate Investigators: Dr. John R. Claybaugh, Ph.D.; Dr. Nadine Wilson, Ph.D.	
Department/Section: Clinical Investigation/Physiology	
Key Words: atrial natriuretic peptides (ANP)	
Funding: FY 87: NA	FY 88: \$3,084.
Gifts:	Periodic Review Date: Apr 88 Decision: Continue

OBJECTIVE: The purpose of the proposed experiments is to extend our current investigations on the effects of atrial natriuretic peptides (ANP) on sodium transport in kidneys as follows: (1) To use "stop-flow" analysis in an attempt to locate the tubular level at which extra-luminal sodium enters the nephron. (2) To measure the effects of ANP on simultaneous indicator dilution curves for sodium and inulin in a rat model of an ANP-resistant salt and water retaining state (Adriamycin nephrosis) using innervated or denervated kidneys.

TECHNICAL APPROACH: Because of ^{22}Na disposal problems possibly occurring, the more difficult approach utilizing an isolated kidney was developed. The first steps in validating the function of the kidney included the clearance of creatinine, Na, and K, and the determination of effects of vasopressin and its clearance. This has yielded interesting results regarding vasopressin clearance which we are presently pursuing before continuing on to the original sodium handling questions we were after.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Progress (through August 88): To date we have successfully developed an isolated perfused rat kidney preparation that is physiologically functional for a period of about two hours. This is in agreement with previous publications. In 6 preliminary experiments we have established that these kidneys are responsive to vasopressin in that they produce a more concentrated urine when vasopressin is in the media. We have also determined that vasopressin is metabolized by at least two mechanisms in this preparation. First via filtration and excretion, but approximately 10 fold more via other renal mechanisms presumably in the vasculature. We are planning to determine specificity of these metabolic systems and the effects of vasopressin concentration in the short term, and then begin studies on ANF and sodium handling. An abstract on the vasopressin metabolism will be submitted for the spring FASEB meetings.

Detail Summary Sheet

Prot No: 37A86	Status: Completed
TITLE: Preparation of a Vasotocin-Specific Antiserum in New Zealand White Rabbits for the Development of a Radioimmunoassay	
Principal Investigator: Catherine Uyehara, Ph.D.	
Associate Investigators: John R. Claybaugh, Ph.D.; Aileen K. Sato, Med Tech	
Department/Section: Clinical Investigation/Physiology	
Key Words: vasotocin-specific antiserum	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Sep 88
	Decision: Completed

OBJECTIVE: To develop a radioimmunoassay for the measurement of vasotocin by preparation of a vasotocin-specific antiserum.

TECHNICAL APPROACH: A conjugation of VT bovine thyroglobulin and carbodiimide is prepared, diluted with 0.9% saline, and then emulsified with Freund's complete adjuvant. One ml of this solution is injected SQ over the dorsal thoracic and lumbar areas 5 times at 10-day intervals. Approximately one week later the rabbit is bled via an ear artery to test for a sufficient antiserum titer level. Booster shots are given at 10-day intervals until a sufficient antiserum titer level is attained. At this point, a 100 ml of whole blood is drawn by cardiac puncture while the animal is under Ketamine anesthesia. The animal is then euthanatized by injection of T-61.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

All immunizations were completed, the rabbits sacrificed, and the evaluation and use of the antisera will continue for several years.

Detail Summary Sheet

Prot No: 11A87	Status: Ongoing
TITLE: The Metabolic Clearance of Arginine Vasopressin in the Amniotic Sac of the Fetal Guinea Pig	
Principal Investigator: John R. Claybaugh, Ph.D. (formerly: Catherine F.T. Uyehara)	
Associate Investigators: MAJ Gerard Letterie, Aileen K. Sato, Linda Kullama	
Department/Section: Clinical Investigation	
Key Words: arginine vasopressin	
Funding: FY 87: \$2,000. FY 88: \$1,273.	Periodic Review Date: Oct 87
Gifts:	Decision: Continue

OBJECTIVE: To demonstrate that the amniotic sac is a major site of fetal AVP clearance. Further, we will determine where in the amniotic sac AVP metabolism occurs (via amniotic fluid enzymes and/or via amniotic membrane receptors), explore the kinetics of this metabolic process, and characterize the metabolites produced.

TECHNICAL APPROACH: Vasopressin, either unlabelled or labelled with tritium-will be injected into the amniotic sac while the maternal guinea pig is under anesthesia and the fate of the vasopressin relative to insulin will be assessed by HPLC and radioimmuno assay. In vitro experiments will be conducted to determine the sites of vasopressin metabolism and action.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA
The other product is not yet identified, but possesses a phenylalanine amino acid and is therefore comprised of components of the "ring" portion of the molecule. The enzyme in the fluid has been identified a "trypsin-like" enzyme, the first such description of such an enzyme metabolizing vasopressin. Further work will continue on the identification of metabolite that appears to be membrane dependent. To date the following publications have resulted from this protocol:

Uyehara, CFT, and JR Claybaugh. Vasopressin, vasotocin, cortisol, and electrolyte concentrations in guinea pig amniotic fluid. Fed. Proc. 44:463 (abst # 306), 1985.

Uyehara, CFT, and JR Claybaugh. Metabolism of vasopressin in the amniotic sac of the fetal guinea pig. Fed. Proc. 46:797 (abst # 2804), 1987.

Uyehara, CFT. The metabolic clearance of arginine vasopressin in the amniotic sac of the fetal guinea pig. Ph.D. Thesis, Department of Physiology, University of Hawaii, 1987.

Uyehara, CFT, and JR Claybaugh. Evidence that vasopressin is metabolized by a trypsin-like enzyme in guinea pig amniotic fluid. FASEB J 2:A1483 (abst # 6893), 1988.

Uyehara, CFT, and JR Claybaugh. Vasopressin metabolism in the amniotic sac of the fetal guinea pig. Endocrinology (in press)

Detail Summary Sheet

Prot No: 9H88	Status: Ongoing
TITLE: A Comparison of Complete Maxillary Denture Retention Before and After Magnetic Retention is Obtained Utilizing Osseointegrated Implants	
Principal Investigator: MAJ Gregory W. Boice, DC	
Associate Investigators:	
Department/Section: Dental Activity	
Key Words: osseointegrated implants	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Dec 87 Decision: Continue

OBJECTIVE: To measure the in vivo retention that is added to complete maxillary dentures by using rare earth magnets in conjunction with osseointegrated implants.

TECHNICAL APPROACH: Patients were selected on the basis of having an edentulous maxillary ridge and a suitable maxillary denture. A stainless bar was fixed to the palatal portion of the denture and reinserted into the patients' mouth. Using a Chattilion push-pull gauge, the patients' denture was pulled down and the force needed to break the seal was recorded. After those measurements were taken, 2 Interpore IMZ Titanium Endosseous implants were placed, 1 each at the maxillary canine area. The implants were allowed four months to osseointegrate then were uncovered and keepers were attached to the implants. Then 2 Jackson regular rare-earth magnets were placed in the patients' dentures in such away to achieve contact with the keepers when the dentures were fully seated. Pull out measurements were done after magnetic augmentation in the same way as before.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

Twelve subjects had the initial measurements done and subsequently had the implants placed. The quality of the bone was noted during implant placement. To date, eleven subjects have their implants uncovered for a total of 22 implants uncovered. Of those 22 implants, 2 failed to osseointegrate; one each on two different people. It is interesting to note that these two individuals had dehiscence over the mucosa over the implant in less than one month's time. Also both patients were heavy smokers. On one of the patients who lost an implant, developed essentially a periodontal abcess around the remaining implant due to excess soft tissue and underwent a secondary procedure to place the soft tissue at a lower level on the implant. Nine patients have had the magnets placed and have had the subsequent pull down studies. The initial feeling by me is that the quantitative data does not show a marked increase in retention. No statistical analysis has been done yet. The patients, however, have indicated significant subjective improvement in denture retention and stability.

Detail Summary Sheet

Prot No: 27A87	Status: Completed
TITLE: Earliest Optimal Prosthetic Loading Time for IMZ, Titanium Sprayed, Implants In the Mandible and Maxilla of Goats	
Principal Investigator: MAJ Jeffery Dootson, DC	
Associate Investigators: COL Richard A. Kraut, DC; LTC Harvey Kessler, DC	
Department/Section: Dentistry	
Key Words: prosthetic, titanium implants	
Funding: FY 87: NA	FY 88: \$800.
Gifts:	Periodic Review Date: Jun 88 Decision: Completed

OBJECTIVE: To determine the time required to achieve histological evidence of osteointegration of sprayed titanium (IMZ) implants in the maxilla and mandible of adult edentulous goats.

TECHNICAL APPROACH: 18 adult goats have been rendered partially edentulous. After four months of healing, titanium implants and hydroxyapatite will be implanted in all four edentulated areas of each goat. The goats will be sacrificed at predetermined periods and the degree of integration of the implants determined.

PROGRESS: No. of Subjects Enrolled - To Date: 18 Reporting Period: 18

All 18 goats have survived the edentulation phase of the project. Two goats were radiographed three months following edentulation, and based on their rate of healing, it is anticipated that the implants will be placed four months following edentulation (end of November, early December 1987).

Project is complete except for final data analysis and publication.

Detail Summary Sheet

Prot No: 41H85

Status: Completed

TITLE: Comparison of Sublimaze Citrate in Intravenous Conscious Sedation for Outpatient Oral Surgery

Principal Investigator: COL Richard A. Kraut, DC

Associate Investigators:

Department/Section: Dentistry/Oral Surgery

Key Words: oral surgery; conscious sedation

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Aug 88

Gifts: None

Decision: Completed

OBJECTIVE: To compare the blood pressure, pulse, respiratory rate, PtcO₂ and PtcCO₂ in patients sedated with sublimaze versus sufentanil citrate for surgical removal of impacted wisdom teeth.

TECHNICAL APPROACH: Fifty consecutive volunteer ASA I patients who present to the Oral Surgery Clinical requiring removal of at least one maxillary and one mandibular impacted wisdom tooth and who request intravenous sedation will constitute the study group. Twenty-five patients will be randomly selected for each of the two study groups. Management will be the same for the two groups except that Group A patients will be sedated with sublimaze and diazepam. Group B patients will be given sufentanil citrate. Descriptive statistical analysis of blood pressure, pulse, respiratory rate, PtcO₂ and PtcCO₂ will be carried out.

PROGRESS: No. of Subjects Enrolled - To Date: 50 Reporting Period: 50

All 50 patients have been treated without complication. Data has just been analyzed. Final report in press.

Detail Summary Sheet

Prot No: 10H86	Status: Completed
TITLE: Osteointegrated Implants Coated with Hydroxylapatite in the Treatment of Edentulous Jaws	
Principal Investigator: COL R. A. Kraut	
Associate Investigators: LTC Dennis R. Skirvin, DC; LTC Kenneth J. Juhar, DC; MAJ Alan F. Shernoff, DC	
Department/Section: Dentistry	
Key Words: edentulous mandibles; implants	
Funding: FY 87: NA	FY 88: \$12,870.
Gifts: None	Periodic Review Date: Nov 87 Decision: Completed

OBJECTIVE: To determine the biocompatibility and prosthetic effectiveness of hydroxylapatite-coated osteointegrated implants in edentulous mandibles and to determine patient satisfaction with implant-stabilized mandibular dentures.

TECHNICAL APPROACH: Ten adult patients meeting the protocol criteria will be enrolled. Patients will undergo the placement of four to six osteointegrated implants while under local anesthesia and IV sedation. AP and lateral cephalometric radiographs and panographs will be obtained to determine the size and location of the implants. The implants will be exposed and loaded after three months of osteointegration. Upon placement of the transoral component of the implant, the prosthodontist will fabricate an implant supported and retained mandibular denture. Biocompatibility will be assessed by implant survival, panographic radiographs, and periodontal evaluation. Patient satisfaction will be assessed via a questionnaire at 1 and 10 months after insertion.

PROGRESS: No. of Subjects Enrolled - To Date: 10 Reporting Period: 10
Study completed. No adverse effects reported and data analysis in progress.

Detail Summary Sheet

Prot No: 19H84	Status: Ongoing
TITLE: Treatment of Graves' Ophthalmopathy with Cyclosporin	
Principal Investigator: COL Michael Bornemann, MC	
Associate Investigators:	
Department/Section: Medicine/Endocrine-Metabolic	
Key Words: Graves' ophthalmopathy	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jul 88
Gifts: None	Decision: Continue

OBJECTIVE: To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' disease.

TECHNICAL APPROACH: This is a random crossover study comparing Cyclosporin therapy of Graves' ophthalmopathy versus the standard of current therapy, high-dose oral Prednisone. Because of potential toxicity, this is not a double-blind study. The drugs will be administered for three weeks each, and then the patient will be crossed over with clinical response measured by an ophthalmopathy index. There will be a pretherapy clinical assessment and the usual laboratory testing pre-, post-, and during therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This Walter Reed collaborative protocol remains open anticipating any patients that might meet the study population criteria.

Detail Summary Sheet

Prot No: 31H86	Status: Ongoing
TITLE: The Incidence of Clinically Relevant IgE-Hypersensitivity to Mold Spores in Hawaii	
Principal Investigator: MAJ Robert E. Bowen, MC	
Associate Investigators: MAJ William F. Long, MC	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: mold spores	
Funding: FY 87: NA FY 88: \$270.	Periodic Review Date: Mar 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine whether or not the recently developed extracts of the mold spores, Myxomycetes, Basidiomycetes, and imperfect fungi represent clinically significant aeroallergens in Oahu.

TECHNICAL APPROACH: Two hundred adult patients will be skin-tested for common Hawaiian aeroallergens. In addition, nine spore extracts will be tested. Prick testing will be done first using a template on the back to insure uniformity. This will permit comparison with the three whole body imperfects. At the completion, the data will be collated.

PROGRESS: No. of Subjects Enrolled - To Date: 24 Reporting Period: 24

No adverse effects; skin testing without complication. Prick skin tests suggests extracts c/w clinically relevant IgE - mediated reaction, but much too soon to collate data. Ongoing protocol. Awaiting additional extracts from Walter Reed Army Medical Center. Anticipate conclusion within 6 months.

Detail Summary Sheet

Prot No: 22H88

Status: Ongoing

TITLE: "Double Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock"

Principal Investigator: COL Joel Brown, MC

Associate Investigators: COL Jeffrey L. Berenberg, MC; MAJ Gerald R. Harrington, Jr., MC; MAJ Phillip P. Bruno, MC; MAJ Gary P. Jones, MC; MAJ Iris J. West, AN.

Department/Section: Medicine/Infectious Disease

Key Words: gram-negative sepsis/gram-negative septic shock

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Mar 88

Gifts:

Decision: Ongoing

OBJECTIVE: To test whether antibody against endotoxin core subfraction offers a safe treatment for septic shock.

TECHNICAL APPROACH: The multicenter study plans to enroll between 45 and 450 patients, with 50 patients at TAMC. Patients with sepsis or septic shock will be given a vial that contains either the antibody or a human serum albumen placebo. The code can be broken by rubbing a blackened area of the label with an alcohol pad.

PROGRESS: No. of Subjects Enrolled - To Date: 0

Reporting Period: 0

Study approved and funded at end of FY.

Detail Summary Sheet

Prot No: 33H86	Status: Ongoing
TITLE: The Natural History of HTLV-III Infection and Disease in a United States Military Population	
Principal Investigator: COL Joel D. Brown, MC	
Associate Investigators: MAJ Robert Gates, MC	
Department/Section: Medicine/Infectious Disease Service	
Key Words: HTLV-III; AIDS; infection	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Mar 88
Gifts: None	Decision: Pending Funding

OBJECTIVE: To assess the impact of HTLV-III infection on military readiness by defining the natural history of infection in the general military population and to form a study cohort upon which subsequent studies can be built.

TECHNICAL APPROACH: Personnel with confirmed HTLV-III infection who agree to participate will receive standard evaluation, counseling, and referral of contacts. Information will be centralized in a common data base. Serum and CSF samples will be stored at WRAIR for future testing. Follow-up studies will be performed every six months.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Funding probably not forthcoming.

Detail Summary Sheet

Prot No: 55H88

Status: Ongoing

TITLE: A Direct Comparison Between the Cholesterol Lowering Effects of
Psyllium Mucilloid and Bile Sequestering Agents

Principal Investigator: CPT Gary D. Gazenski, MC

Associate Investigators: CPT Steven E. Hill, MC; MAJ Gerald R. Harrington, MC
CPT Noreen M. Cohen, SP

Department/Section: Medicine

Key Words: psyllium mucilloid;

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Aug 88

Gifts:

Decision: Continue

OBJECTIVE: To show that psyllium mucilloid is more efficacious than the bile sequestrant cholestyramine in reducing total serum cholesterol and low density lipoprotein.

TECHNICAL APPROACH: Two arm outcome study of approved medications.

PROGRESS: No. of Subjects Enrolled - To Date:

Reporting Period:

New start.

Detail Summary Sheet

Prot No: 54H88	Status: Ongoing
TITLE: A Prospective, Randomized, Double-Blind, Placebo Controlled Study of the Effects of 6 Months of Enalapril on Microalbuminuria in Patients with Insulin-Dependent Diabetes Mellitus	
Principal Investigator: CPT Rosemary Fitzpatrick, MC	
Associate Investigators: MAJ L. Harrison Hassell, MC; Dr. Craig Holland, M.D. CPT Robert A. Decker, MC	
Department/Section: Medicine	
Key Words: diabetes mellitus;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: *	Periodic Review Date: Aug 88 Decision: Continue

OBJECTIVE: To see if Enalapril will decrease rate of microalbuminuria in patients with Insulin-Dependent Diabetes Mellitus.

TECHNICAL APPROACH: Randomized placebo controlled double-blind study with approximately 30 patients in control groups; 30 in treatment group. Control group receives placebo. Test group receives 5 mg Enalapril 4 times a day. Following patients- glucose control, GFR, timed basal urines for microalbuminuria. Compare test and control group.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

*Study referred via USUHS to HMJF for outside funding.

Detail Summary Sheet

Prot No: 8L87

Status: Ongoing

TITLE: Noncompliant Behavior Among Hemodialysis Patients: Relationship to Disturbances of the Renin-Angiotensin-Aldosterone, Antidiuretic Hormone, and Atrial Natriuretic Hormone Axes

Principal Investigator: MAJ L. Harrison Hassell, MC

Associate Investigators: John R. Claybaugh, Ph.D.; Arnold Siemsen, MD;
Jon Streltzer, MD

Department/Section: Medicine/Nephrology

Key Words: hemodialysis patients

Funding: FY 87: NA

FY 88: \$2,851.

Periodic Review Date: Oct 88

Gifts: none

Decision: Continue

OBJECTIVE: Designed to compare levels of plasma renin activity (PRA), aldosterone (PA), antidiuretic hormone (ADH), and human atrial natriuretic peptide (hANP) in compliant and noncompliant hemodialysis patients to those in both humans and experimental animals associated with stimulation of thirst and salt appetite. Abnormalities of these hormonal axes may provide inferential evidence of disturbances of thirst and salt appetite which may underlie noncompliant behavior.

TECHNICAL APPROACH: Hemodialysis patients have blood drawn before and after two consecutive hemodialysis treatments. Urine is collected in the interim to calculate residual renal function. Patients have been categorized according to pre-defined criteria of compliance as assessed by interhemodialytic weight gain. The study will evaluate relationships of normal abnormalities to compliant and noncompliant behavior.

PROGRESS: No. of Subjects Enrolled - To Date: 9

Reporting Period: 1

No adverse effects have occurred. The data has been presented in seminar format for peer review to the DCI, TAMC. An abstract is planned for the 1989 FASEB meeting. There is great difficulty locating patients for the complaint group.

Detail Summary Sheet

Prot No: 26H87	Status: Ongoing
TITLE: Effect of Hemodialysis on Hearing Threshold	
Principal Investigator: MAJ L. Harrison Hassell, MC	
Associate Investigators: CPT Raymond J. Enzenauer, MC; MAJ Jeffrey W. Davies, MSC	
Department/Section: Medicine	
Key Words: hemodialysis; hearing threshold;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Sep 88 Decision: Continue

OBJECTIVE: To assess the acute effect of a standard hemodialysis procedure and various modifications to include changing dialysate sodium concentration, replacement of solute loss with mannitol, and separating solute and fluid removal on middle and inner ear function.

TECHNICAL APPROACH: Lab studies (electrolytes, BVN, Cr, Osmolality Glucose, Calcium, Magnesium, Phosphorus), determination of hearing threshold, and tympanograms are performed before and after a "standard" or usually prescribed hemodialysis treatment. Phase III requires CIC approval; therefore, no patients have been enrolled.

PROGRESS: No. of Subjects Enrolled - To Date: 9 Reporting Period: 9

No adverse effects have occurred. Data has not been analyzed due to insufficient patient numbers.

Detail Summary Sheet

Prot No: 27H88	Status: Ongoing
TITLE: A Treatment Protocol for the Use of Trimetrexate with Leucovorin Rescue for AIDS Patients with <u>Pneumocystis Carinii</u> Pneumonia and Serious Intolerance to Approved Therapies	
Principal Investigator: Dr. Arthur C. Johnson, M.D. Associate Investigators: COL Joel D. Brown, MC	
Department/Section: Medicine/Infectious Disease	
Key Words: Leucovorin; <u>Pneumocystis Carinii</u> pneumonia (PCP);	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Apr 88 Decision: Continue

OBJECTIVE: To make available this treatment approach to our patients pending FDA approval. to add to existing information on the safety and efficacy of trimetrexate with leucovorin rescue in AIDS patients with Pneumocystis UCarinii pneumonia (PCP) who have no therapeutic alternatives because they have demonstrated serious (severe or life threatening) intolerance to both conventional therapies for PCP.

TECHNICAL APPROACH: Treatment protocol (national).

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Detail Summary Sheet

Prot No: 10H88 Status: Ongoing

TITLE: Assessment of Nonspecific Decrease in Skin Test Reactivity and Late Phase Reactions During Immunotherapy

Principal Investigator: MAJ Marcia L. Muggelberg, MC

Associate Investigators:

Department/Section: Medicine/Allergy-Immunology Service

Key Words: immunotherapy

Funding: FY 87: NA FY 88: \$800. Periodic Review Date: Dec 87

Gifts: None Decision: Continue

OBJECTIVE: To determine whether there is a nonspecific decrease in skin test reactivity to unrelated extracts during immunotherapy and to determine the effect of immunotherapy on the late response.

TECHNICAL APPROACH: Observational study of skin test changes during indicated immunological treatment.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 11H88	Status: Ongoing
TITLE: Efficacy of Steroids in the Acute Treatment of Asthma: Are Duration of Symptoms Important?	
Principal Investigator: MAJ Marcia L. Muggelberg, MC	
Associate Investigators: MAJ T. R. Vaughan, MC	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: efficacy of steroids; asthma	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Dec 87 Decision: Continue

OBJECTIVE: To determine whether the efficacy of steroids for the treatment of asthma in the acute setting is related to the duration of the patients' symptoms for that episode of asthma.

TECHNICAL APPROACH: Prospective data collection; standard patient care.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:
New start.

Detail Summary Sheet

Prot No: 12H88	Status: Ongoing
TITLE: Multicenter Clinical Evaluation of Penicillin Skin Testing Materials	
Principal Investigator: MAJ Marcia L. Muggelberg, MC	
Associate Investigators:	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: penicillin allergy	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Dec 87 Decision: Continue

OBJECTIVE: 1) To determine whether there is a difference in the incidence of skin test positivity to the different skin testing reagents prepared by different methods in patients with a history of penicillin allergy as well as in subjects with no previous history of an adverse reaction to a penicillin-like drug. 2) To study the comparative potency, as determined by cutaneous endpoint titration skin testing, of reagents prepared by different methods in skin test positive patients. 3) To compare skin test reactivity to freshly reconstituted reagents with that produced by aged reagents.

TECHNICAL APPROACH: Test-arm trials.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 2H86	Status: Ongoing
TITLE: Systolic Hypertension in the Elderly Program	
Principal Investigator:	COL Garold L. Paul, MC (formerly: MAJ Victoria Rains, MC)
Associate Investigators:	Dr. Helen Petrovitch, M.D. (Principal Investigator in Hawaii for the national SHEP study)
Department/Section: Medicine	
Key Words: hypertension	
Funding: FY 87: NIH*	FY 88: NIH*
Gifts: None	Periodic Review Date: Oct 88 Decision: Continue

OBJECTIVE: To assess whether long-term administration of antihypertensive therapy to elderly subjects with isolated systolic hypertension reduces the combined incidence of fatal and nonfatal stroke.

TECHNICAL APPROACH: The study will be a double-blind, placebo-controlled, randomized clinical trial. Half of the participants will be given active intervention using a step-up treatment program. The other half will be randomly assigned to placebo.

PROGRESS: No. of Subjects Enrolled - To Date: 19 Reporting Period: 0

Since its inception in Mar 1985, the SHEP Study has randomized a total of 4,736 patients to treatment or placebo. Of these patients, 342 are in the state of Hawaii. Recruitment at TAMC begin in March 1986 and was completed in December 1987. A total of 19 patients were recruited at TAMC, of which 10 are actively being followed at TAMC, and the remaining 9 are being followed at Kaiser or Strab because of convenience for the patients. The study is expected to continue until August 1991, at which time the double-blind will be broken. Tripler will continue its involvement until the termination of the study.

* (Division of Heart, Lung and Blood)

Detail Summary Sheet

Prot No: 30H86	Status: Terminated
TITLE: Bone Loss in the Elderly. Ancillary Study to Systolic Hypertension in the Elderly Program	
Principal Investigator: CPT Timothy R. Roy, MC (formerly: MAJ Victoria Rains, MC)	
Associate Investigators:	
Department/Section: Medicine	
Key Words: hypertension; bone loss; osteoporosis	
Funding: FY 87: NA	FY 88: \$800.
Gifts: Bone density determinations	Periodic Review Date: Mar 88 Decision: Terminate

OBJECTIVE: To determine what factors are involved in the development of osteoporosis and the effect of thiazide-like diuretics in retarding bone loss.

TECHNICAL APPROACH: Participants in this study will answer questions regarding potential risk factors for osteoporosis. Either clorthalidone or a placebo will be given to the patients. Dual photon densitometry of the spine and single photon densitometry of the dominant forearm, ulna, radius, dominant heel will be done at baseline, annually, and at completion of the project (4-6 years).

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No patients have been or will be recruited for this study.

Detail Summary Sheet

Prot No: 37H85

Status: Ongoing

TITLE: Nutritional Support of the Hospitalized Patient: A Comparison Between Continuous and Intermittent Administration of Enteral Tube Feedings

Principal Investigator: CPT Theresa A. Taylor, AN
(formerly: 1LT Leslie R. Kalbach, AN)

Associate Investigators:

Department/Section: Nursing

Key Words: enteral tube feeding

Funding: FY 87: NA FY 88: \$800.

Periodic Review Date: May 88

Gifts: None

Decision: Continue

OBJECTIVE: To ascertain which mode of tube feeding administration, intermittent or continuous, is optimal for the hospitalized patient in regard to maximizing the benefits of nutritional support and minimizing adverse reactions.

TECHNICAL APPROACH: Subjects for the study are selected from a surgical ward population of patients and must meet the criteria of being unable or unwilling to consume caloric needs by p.o. intake alone. Patients from both the otorhinolaryngology and neurosurgical services are considered and entered into the study if enteral tube feeding nutritional support is indicated, and patients are randomly assigned to either mode of administration. After one week of the initial mode of administration, the patient is changed to the alternate mode for another week. Data is collected by nursing staff responsible for the care of the patient per intake and output worksheets and study-specific data sheets. If patients demonstrate a desire to eat, they must be eliminated from the study.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

Re-start pending new principal investigator.

Detail Summary Sheet

Prot No: 32H88	Status: Ongoing
TITLE: Vasoconstriction and Anesthesia for Intranasal Surgery: Is Cocaine Really Necessary?	
Principal Investigator: CPT Terry C. Wicks, ANC	
Associate Investigators: CPT Timothy A. Newcomer, AN MAJ Marc A. Paradis, MC	
Department/Section: Anesthesiology Nursing Section, Department of Nursing	
Key Words: intranasal surgery; vasoconstriction;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88 Decision: Continue

OBJECTIVE: To examine whether or not 4% lidocaine with 0.002% oxymetazoline can provide anesthesia and vasoconstriction comparable to 4% cocaine when applied topically. Is ephinephrine in a concentration of 1:200,000 as effective in reducing blood in the operative field as epinephrine 1:50,000 when infiltrated into nasal tissue?

TECHNICAL APPROACH: Double blind, treatment arm trial of standard, in use procedures.

PROGRESS: No. of Subjects Enrolled - To Date: 6 Reporting Period: 6

Since 10 August, six subjects have been enrolled and studied. Thus far, anesthesia and vasoconstriction for all subjects in this double blind study has been acceptable.

Detail Summary Sheet

Prot No: 44H87	Status: Ongoing
TITLE: An Investigation of the Possible Transmission of Hepatitis A by Transfusion of Infectious Blood Products at Tripler Army Medical Center	
Principal Investigator: MAJ Lawton A. Seal, Ph.D., MS	
Associate Investigators: CPT Kraig S. Lerud, MC, CPT Michael A. Riel, MC, COL Robert B. Hill, MC	
Department/Section: Department of Pathology & Area Laboratory Services/ Microbiology/Immunology	
Key Words: Hepatitis A virus (HAV)	
Funding: FY 87: NA	FY 88: NA
Gifts: None	Periodic Review Date: Dec 87 Decision: Continue

OBJECTIVE: To assay for the presence of hepatitis A virus (HAV) in blood products obtained from an infected donor and to monitor the status of the recipient of these potentially infectious products in regard to the presence of HAV specific antibodies (abs) or antigen (agn).

TECHNICAL APPROACH: Viral isolation and immunological assay of patient samples.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New Start.

Detail Summary Sheet

Prot No: 30H88	Status: Ongoing
TITLE: SYVA COMPANY - Microtrak HSV Culture Identification Test Premarket Evaluation Trial	
Principal Investigator: MAJ Lawton A. Seal, MS	
Associate Investigators: CPT Kathleen M. Fleet, MC; Ms. Patricia Toyama, M.S. COL Robert B. Hill, MC; COL Joseph C. Woods, MC	
Department/Section: Pathology and Area Laboratory Services	
Key Words: HSV culture;	
Funding: FY 87: NA	FY 88: NA
Gifts: *\$3,213.	Periodic Review Date: Jun 88 Decision: Continue

OBJECTIVE: To compare the overall accuracy of the Microtrak HSV Culture Identification Reagent, using a centrifugation-enhanced shell vial, to conventional cell culture methods in use at Tripler for identification of HSV antigen obtained from clinical specimens.

TECHNICAL APPROACH: Laboratory quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

*Request for outside support referral via USUHS to HMJF.

Detail Summary Sheet

Prot No: 46H88	Status: Ongoing
TITLE: Evaluation of the Pathogene Identification Kit - An in situ DNA Probe for Herpes Simplex Virus (HSV)	
Principal Investigator: MAJ Lawton A. Seal, MS	
Associate Investigators: MAJ Merle S. Sprague, MC; COL Joseph C. Woods; COL Robert B. Hill, MC; Ms. Patricia Toyama, M.S.	
Department/Section: Pathology and Area Laboratory Services	
Key Words: Herpes Simplex Virus (HSV)	
Funding: FY 87: NA	FY 88: NA
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To compare the sensitivity and specificity of this newly developed method of detecting HSV in clinical material to that of a standard culture method as outlined in TAMC Protocol No. 21H88 and a modified culture method as described in TAMC Protocol No. 30H88.

TECHNICAL APPROACH: The technical approach involves the case of tissue culture and electron microscopic analysis of concentrated blood products obtained from a hepatitis A infected donor.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

The recipient of the potentially contaminated blood products (platelets) was lost to followup at the 121st Evac Hospital upon her return to the ROK. No additional data are available on this patient. Experiments are underway involving electron microscopic analysis of the concentrated blood plasma. Final and complete evaluation of all collected data is forthcoming.

Detail Summary Sheet

Prot No: 21H88	Status: Ongoing
TITLE: Use of Maternal Serum IgG Antibody Titer as an Assessment of the Risk of Infection with Herpes Simplex Virus (HSV) to the Unborn Infant	
Principal Investigator: MAJ Merle S. Sprague, MC	
Associate Investigators: CPT Beau J. Freund, MS; COL Kunio Miyazawa, MC; MAJ Jerome N. Kopelman, MC; COL Joseph C. Woods, MC; COL Robert B. Hill, MC; CPT Kraig S. Lerud, MC; Patricia S. Toyama, M.S.	
Department/Section: Pathology and Area Laboratory Services	
Key Words: maternal serum igG antibody titer; herpes simplex virus (HSV);	
Funding: FY 87: NA	FY 88: NA
Gifts: *\$85,639.	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: The primary objective of this project is to test the possibility that obstetricians may be able to simplify their management of patients with herpes simplex virus infection during pregnancy. Instead of cumbersome culturing procedures, results from this project may provide evidence that ordering two sequential herpes serologies during the course of the pregnancy may provide an alternative and easier method of predicting the susceptibility of an infant to herpes neonatorum based on maternal antibody status.

TECHNICAL APPROACH: Laboratory quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

*Request for outside support referred via USUHS to HMJF.

Detail Summary Sheet

Prot No: 14H88	Status: Ongoing
TITLE: Use of the PGE2 vaginal suppository in cervical ripening and/or labor induction	
Principal Investigator: CPT Stephen J. Andrews, MC	
Associate Investigators: MAJ Robert W. Smith, MC; MAJ Jerome N. Kopelman, MC; COL Kunio Miyazawa, MC	
Department/Section: Obstetrics & Gynecology	
Key Words: PGE2 vaginal suppository;	
Funding: FY 87: NA	FY 88: \$800.
Gifts:	Periodic Review Date: Jun 88 Decision: Continue

OBJECTIVE: Establish the efficacy and safety for the term parturient and her fetus of the PGE2 vaginal suppository (3.0 mg) as an inducing and ripening agent for unripe cervixes.

TECHNICAL APPROACH: Patient with medical or obstetric indication for induction with unripe cervix will be randomized to either Pitocin induction vs PGE2 suppository. Resident and staff assigned to Labor and Delivery will follow patient according to protocol and neonate will be followed in newborn nursery according to protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0
New start.

Detail Summary Sheet

Prot No: 47H88	Status: Ongoing
TITLE: Uterine and Umbilical Artery Blood Flow Change in Cesarean Section Under Subarachnoid Block	
Principal Investigator: MAJ Joseph P. Bruner, MC	
Associate Investigators: COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: subarachnoid blood;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88
	Decision: Continue

OBJECTIVE: The purpose of the present study is to measure changes in uterine and umbilical artery blood flow velocity waveforms that occur during administration of subarachnoid block in doses adequate to perform delivery by cesarean section. Conduction anesthesia is commonly employed for obstetric pain relief. The anesthetic agents used can be sympatholytic, however, and thus effect resting vascular tone.

TECHNICAL APPROACH: All patients admitted to the labor floor for scheduled repeat Cesarean section under subarachnoid block will be eligible to participate in the study. Data descriptive of the patient population and anesthesia procedure will be collected. Subarachnoid block will be administered according to established protocol and observing recognized guidelines of intravenous access, fluid volume preload, maintenance of physiologic blood pressure, and left uterine displacement. Baseline uterine and umbilical artery flow velocity waveforms will be recorded after the fluid load, and again after an anesthetic level of T₁₀ to L₄ has been obtained.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: 48H88	Status: Ongoing
TITLE: Continuous Instantaneous Assessment of the Adequacy of Fetal Cerebrovascular Perfusion by Means of Transvaginal Continuous Wave Doppler Ultrasonography of the Fetal Anterior Cerebral Arteries Through the Anterior Fontanelle	
Principal Investigator: MAJ Joseph P. Bruner, MC Associate Investigators: COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: fetal anterior cerebral arteries;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: The purpose of the present study is: (1) to determine the feasibility of continuous transvaginal Doppler ultrasonography of the fetal anterior cerebral arteries during labor and delivery; (2) to determine the best means of fetal anterior cerebral artery waveform analysis for clinical applications; (3) to correlate recorded flow velocity waveforms with methods of intrapartum fetal surveillance currently in use; (4) to assess the desirability of developing a prototype for an integrated Intrapartum Fetal Surveillance Monitor.

TECHNICAL APPROACH: After cerebral artery flow velocity wave forms measured manually during labor, delivery and the neonatal period and compared to known standards.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: 33H88	Status: Ongoing
TITLE: Cefamandol Irrigation vs. Parenteral Cefadyl or Cefoxitin Prophylaxis and the Relationship of Bladder Flap Closure to the Incidence of Postpartum Endometritis	
Principal Investigator: CPT John W. Byron, MC	
Associate Investigators: CPT Michael D. Bork, MC, MAJ Jerome N. Kopelman, MC COL Kunio Miyazawa, MC	
Department/Section: Obstetrics & Gynecology	
Key Words: cefamandol irrigation;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88 Decision: Continue

OBJECTIVE: To determine the effect of bladder flap closure on the incidence of postpartum endometritis as well as the associated complications e.g., abscess formation. Simultaneously, the use of prophylactic antibiotics in our patient population will be examined in order to determine the most effective regimen. Cefamandol irrigation will be compared with Cefoxitin and Cefadyl parenteral antibiotics.

TECHNICAL APPROACH: All patients in Labor and Delivery scheduled for C-section are considered as candidates for random number blindly for and assigned respectively. Bladder flap (open or closed) will be assigned at random according to protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Approved on 31 August 1988.

Detail Summary Sheet

Prot No: 34H88	Status: Ongoing
TITLE: A Prospective Evaluation of Laparoscopic Techniques Verres Needle Insufflation vs. Direct Trocar Insertion	
Principal Investigator: CPT John W. Byron, MC	
Associate Investigators: CPT Glenn R. Markenson, MC; MAJ Milo L. Hibbert, MC; COL Kunio Miyazawa, MC	
Department/Section: Obstetrics & Gynecology	
Key Words: Laparoscopic techniques;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88 Decision: Continue

OBJECTIVE: To compare the efficiency and safety between two laparoscopic techniques in a prospective manner. Determine if direct insertion technique offers benefits of decreased time of surgery and reduction in amount of pneumoperitonium required.

TECHNICAL APPROACH: Patients for the proposed study will come from those undergoing laparoscopic procedures through any of the gynecologic teams: GYN Oncology Team, GYN Team, Family Planning or Infertility Service. Informed consent will be obtained prior to the procedure. Patients will then be randomized into one of the two groups with the procedure to be performed located on the surgeon data sheet. The data sheet will remain sealed until immediately prior to surgery. A data sheet will be completed by the operating surgeon in conjunction with the anesthetist. Data sheets will then be collected by an author who will check them for accuracy and completeness.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Approved on 31 August 1988.

Detail Summary Sheet

Prot No: 8H86	Status: Ongoing
TITLE: Infection Prevention in Patients Undergoing Radical Hysterectomy	
Principal Investigator: COL Kunio Miyazawa, MC	
Associate Investigators:	
Department/Section: Obstetrics and Gynecology/Gynecology Oncology Service	
Key Words: hysterectomy; antibiotics; infection	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Nov 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine the effectiveness of antibiotics (cefamandole) in preventing infectious morbidity of radical abdominal hysterectomy.

TECHNICAL APPROACH: In a double-blind, randomized study patients receive placebo or iv cefamandole prior to the surgical incision and again two hours later.

PROGRESS: No. of Subjects Enrolled - To Date: 28 Reporting Period: 7

A total of 28 cases exists in the current study. There is no clear evidence of difference of morbidity in either group. Will continue study to adequate number accumulation.

Detail Summary Sheet

Prot No: 29T86	Status: Ongoing
TITLE: GYN-Surgical Training Laboratory Using Animal Models (Swine)	
Principal Investigator: COL Kunio Miyazawa, MC	
Associate Investigators:	
Department/Section: Obstetrics and Gynecology/Gynecology Oncology	
Key Words: training	
Funding: FY 87: NA FY 88: \$2,281.	Periodic Review Date: Sep 88
Gifts: None	Decision: Continue

OBJECTIVE: To expose TAMC gynecology residents to procedures performed in the management of gynecologic malignancies and to train them in the management of minor urologic and intestinal complications during gynecologic surgery.

TECHNICAL APPROACH: Pigs will be preanesthetized with Acepromazine, 0.2 mg/kg IM, and Atropine, 0.04 mg/kg IM; sedated with Ketamine HCl, 22 mg/kg IM; and then either (1) anesthetized with sodium pentobarbital iv to effect with additional pentobarbital given as needed to maintain a surgical plane of anesthesia, or (2) anesthesia induced with sodium pentothal and maintained with nitrous oxide and methoxyflurane. All animals will be intubated. All animals will be euthanatized at the end of the laboratory so no postoperative medication is necessary.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Five sessions were held this fiscal year. The objectives were accomplished. It adds a strong impact for OB/GYN residency training program for readiness training. Recommend continuation.

Detail Summary Sheet

Prot No: 17H87	Status: Ongoing
TITLE: Comparison of Pregnancy Rates Using Oil-based and Water-based Contrast Medium in the Evaluation of Tubal Patency	
Principal Investigator: MAJ Gerard S. Letterie, MC	
Associate Investigators: COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: tubal patency	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Feb 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine if the use of oil-based contrast medium in the evaluation of tubal patency enhances fertility when compared to water-based solutions.

TECHNICAL APPROACH: Sixty patients fulfilling the study criteria will be entered into one of two random study groups. Group I patients will have an oil-based contrast medium injected during the intra-operative tubal insufflation and a water based contrast medium will be used in an identical fashion on Group II patients. Effectiveness will be determined by the conception rates for the two groups at the end of a three month period.

PROGRESS: No. of Subjects Enrolled - To Date: 22 Reporting Period: 14

Total of 22 cases entered up to now. Abstract was accepted for presentation for ACOG Armed Forces district meeting in November 1988. Need continuation of study to obtain adequate number of cases.

Detail Summary Sheet

Prot No: 29H87	Status: Ongoing
TITLE: Evaluation of Missed Pills on the Effectiveness of Oral Contraception	
Principal Investigator: MAJ Gerard S. Letterie, MC	
Associate Investigators: LTC James Wilson, MC	
Department/Section: Obstetretics and Gynecology	
Key Words: oral contraception	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Dec 87
	Decision: Continue

OBJECTIVE: To determine if missed pills in an oral contraceptive cycle result in the sequence of follicular maturation and eventual ovulation.

TECHNICAL APPROACH: Ten patients will be assigned to each group on a rotating basis for a total of 20 patients. The study population will consist of volunteers drawn from these patients referred to the Reproductive Endocrinology Service, Department of Obstetrics and Gynecology for tubal reanastomosis. The use of this specific population will enable a manipulation of an oral contraceptive regimen without the risk of pregnancy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No subjects are enrolled as yet. Recommend continuation as vaginal ultrasound probe will become available soon.

Detail Summary Sheet

Prot No: 6H86	Status: Terminated
TITLE: Functional Renal Reserve and Early Detection of Renal Disease in Patients with Limited Joint Mobility and Diabetes Mellitus: A Cross-sectional Study	
Principal Investigator: LTC Richard A. Banks Associate Investigators:	
Department/Section: Pediatrics/Endocrinology	
Key Words: diabetes mellitus	
Funding: FY 87: NA FY 88: NA	Periodic Review Date: Jan 88
Gifts: None	Decision: Terminate

OBJECTIVE: To correlate the degree of renal involvement in patients with insulin dependent diabetes mellitus (IDDM) and limited joint mobility (LJM), using several tests of renal function and reserve.

TECHNICAL APPROACH: The current protocol is essentially unchanged except that five 30-minute urine samples are being obtained between 1 and 3 hours after the ingestion of meat, as opposed to the original two samples. This change was made to ensure detection of transient peaks of creatinine.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 0

Methodology for evaluation of renal function is too crude and inaccurate. Will resubmit protocol once a minimally invasive method for evaluation of renal function is found.
No new patients have been entered since the last review.

Detail Summary Sheet

Prot No: 3H87	Status: Ongoing
TITLE: Serum Phosphate Levels in Necrotizing Enterocolitis of the Newborn	
Principal Investigator: LTC Richard A. Banks, MC	
Associate Investigators: COL Franklin Smith, MC; MAJ Robert Jarrett, MC; MAJ Lynn Whittington, MC	
Department/Section: Pediatrics	
Key Words: neonate, enterocolitis, necrotizing	
Funding: FY 87: NA	FY 88: \$800.
Gifts: none	Periodic Review Date: Oct 87 Decision: Continue

OBJECTIVE: To evaluate the changes in serum phosphate concentrations in neonates with necrotizing enterocolitis (NEC) as a possible marker for the presence and extent of NEC.

TECHNICAL APPROACH: Serum phosphate determination in three groups of patients. NEC, maybe NEC, and not NEC.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have entered into the study as of this time.

Detail Summary Sheet

Prot No: 4H87	Status: Ongoing
TITLE: Immunosuppressive Therapy with Methylprednisolone, Prednisone, and Azathioprine in Patients with Newly Diagnosed Insulin-Dependent Diabetes Mellitus	
Principal Investigator: LTC Richard A. Banks, MC	
Associate Investigators: Janel Silverstein	
Department/Section: Pediatrics	
Key Words: diabetes mellitus, pediatric, ketoacidosis	
Funding: FY 87: NA	FY 88: \$800.
Gifts: Imuran	Periodic Review Date: Oct 87 Decision: Continue

OBJECTIVE: To prevent the progression of autoimmune destruction of the pancreatic islet β -cells in previously undiagnosed diabetic patients presenting with hyperglycemia but without overt ketoacidosis.

TECHNICAL APPROACH: Four randomly assigned treatment arms: 1) steroids and imuran 2) steroids 3) imuran and 4) neither steroids nor imuran; measured against multiple parameters of progression of diabetes.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have met the criteria for entry into the study as of this time.

Detail Summary Sheet

Prot No: 38H87

Status: Ongoing

TITLE: A Comparison of Transdermal Estradiol and Oral Combined Estrogen-Progestin Preparations in the Treatment of Polycystic Ovarian Syndrome

Principal Investigator: LTC Richard A. Banks, MC

Associate Investigators: MAJ Robert M. Lehman, MC;
MAJ Gerard S. Letterie, MC

Department/Section: Pediatrics

Key Words: polycystic ovarian syndrome;

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Sep 88

Gifts:

Decision: Continue

OBJECTIVE: To compare the effects of transdermal estradiol and oral sequential estrogen-progestin preparations in patients with polycystic ovarian syndrome, with emphasis placed on relief of symptoms and occurrence of side effects.

TECHNICAL APPROACH: Two-arm treatment trial of approved treatments.

PROGRESS: No. of Subjects Enrolled - To Date:

Reporting Period:

New start.

Detail Summary Sheet

Prot No: 31H85	Status: Ongoing
TITLE: Treatment of Kawasaki Syndrome with Intravenous Gamma Globulin	
Principal Investigator: COL James W. Bass, MC	
Associate Investigators: Marian E. Melish, M.D.	
Department/Section: Pediatrics	
Key Words: Kawasaki syndrome	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jun 88
Gifts: IV Gamma Globulin	Decision: Continue

OBJECTIVE: In uncontrolled studies involving 70 patients in Japan, high dose (400 mg/kg/day) intravenous gamma globulin administered early in illness for 2-4 days has been reported to decrease the frequency of coronary aneurysms from approximately 20% (historical controls) to 3%. Because of severe methodologic flaws in Japanese studies, we propose a multicenter cooperative controlled trial of the possible benefits of this therapy.

TECHNICAL APPROACH: Children with Kawasaki Syndrome will be recruited into the study within the first 10 days of illness. After ascertainment of diagnosis, children will be randomized to receive I.V. gamma globulin or serve as controls without infusion. Follow-up will consist of repeated history and physical examinations, repeated echocardiograms and laboratory tests of hematology, liver and kidney function, coagulation, and immunology at entry, day 15, day 30, day 90, and one year after onset. Echocardiograms will be evaluated blindly by a committee of cardiologists from all participating centers. Angiograms will be performed on all patients with evidence of coronary aneurysms by echocardiogram or other tests.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

There have been no children hospitalized at Tripler Army Medical Center fulfilling the criteria for the diagnosis of Kawasaki disease during the past year since the last annual report regarding this study. We would, however, like to continue the study so that we may afford our patients the benefit of this mode of treatment and that we may be cooperative and supportive of this research project whose principal investigator, Dr. Marian Melish, is a Professor of Pediatrics at the University of Hawaii.

Detail Summary Sheet

Prot No: 14H87	Status: Ongoing
TITLE: The Evaluation of Early Detection of Group A β -hemolytic Streptococci and Treatment in Index Patients and Household Contacts	
Principal Investigator: MAJ James R. Baugh, MC (formerly: MAJ Robert R. Wittler, MC)	
Associate Investigators: COL James W. Bass, MC; MAJ Lawton A. Seal, MS;	
Department/Section: Pediatrics	
Key Words: streptococcal infection	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Mar 88
Gifts: none	Decision: Continue

OBJECTIVE: To investigate the potential benefit of early detection and treatment in index patients with group A β -hemolytic streptococcal infection and their household contacts with respect to the attack rate of streptococcal pharyngitis within the household.

TECHNICAL APPROACH: Families with a child with group A Strep Pharyngitis C (pharyngitis with a throat culture positive for group A β -hemolytic strep) are randomized into one of two groups. Family members have a throat culture taken at the onset, and then are followed over the ensuing 3 months for any secondary cases of group A strep pharyngitis. Group A families have all household members at the onset receive Penicillin while Group B contacts only receive antimicrodials if they are symptomatic with a positive throat culture. The attack rate of secondary cases of strep pharyngitis is then compared between the two groups.

PROGRESS: No. of Subjects Enrolled - To Date: 20 Reporting Period: 20

We have just received the MIC plates and are doing the first 20 isolates this week (20 May 88). We plan to then do 50-60 isolates per week and complete the study in 6 weeks. Approximately thirty families are enrolled. Dr. Baugh, the new principal investigator, is keeping track of all the data.

Detail Summary Sheet

Prot No: 40H88	Status: Ongoing
TITLE: Infant Pneumonia and Ophthalmia Neonatorum Prevention Project	
Principal Investigator: MAJ. James R. Baugh, MC	
Associate Investigators: MAJ Robert R. Wittler, MC; MAJ Lawton Seal, MS; CPT Everett Gayle, MC; Dr. Niven Marchetti; Dr. Margaret Hammerachlag	
Department/Section: Pediatrics	
Key Words: chlamydia;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: Can the incidence of chlamydia trachomatis infection in the newborn be lowered by a multidosing of regimen of erythromycin ophthalmic ointment.

TECHNICAL APPROACH: Prior to beginning the study, a prevalence survey was done for cervical chlamydia colonization in 100 pregnant women. The survey entailed culture as well as chlamydzyme testing. the results indicate a lower than suspected prevalence which translates into fewer study patients. The study, however, will be done at 2 hospitals which will circumvent Tripler's low study population.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No subjects have been enrolled to date as the prevalence studies were just completed.

Detail Summary Sheet

Prot No: 50H88	Status: Ongoing
TITLE: Impetigo: Bacteriologic Etiology and Comparison of Effectiveness of Penicillin, Erythromycin and Cephalexin	
Principal Investigator: CPT Carl W. Demidovich, MC	
Associate Investigators: MAJ Robert R. Wittler, MC; COL James W. Bass, MC	
Department/Section: Pediatrics	
Key Words: impetigo;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To compare the therapeutic efficacy of penicillin VK versus erythromycin estolate versus cephalexin in the treatment of culture proven superficial skin infections.

TECHNICAL APPROACH: Impetigo, the most common skin infection in children is caused by staph aureus or group A streptococcal bacteria. This study compares treatment efficacy of three randomized antibiotics - erythromycin, penicillin, cephalexin as compared to the specific identified bacteria obtained by culturing the lesion.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:
New start.

Detail Summary Sheet

Prot No: 21H85	Status: Terminated
TITLE: Efficacy of Cholestyramine in Acute Infantile Diarrhea	
Principal Investigator: CPT Michael Henrickson, MC	
Associate Investigator: COL James W. Bass, MC	
Department/Section: Pediatrics	
Key Words: diarrhea, infantile	
Funding: FY 87: NA FY 88: NA	Periodic Review Date: Apr 88
Gifts: None	Decision: Terminate

OBJECTIVE: To determine if cholestyramine reduces the frequency and duration of diarrhea in infants with diarrhea of less than 72 hours' duration.

TECHNICAL APPROACH: Infants 6 months to 2 years of age with diarrhea of less than 72 hours' duration will be randomized to receive either cholestyramine or a placebo for three days to be administered by the parents at home. A record of frequency and approximate volume of stools will be kept by the parents, and the patients will be followed in the pediatric clinic at 3-5 days and 2 weeks after initiation of therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Protocol was terminated by principal investigator, Dr. Michael Henrickson due to poor participant compliance, lack of suitable drug vehicle, and the paucity of meaningful data obtained as of October 1986.

Detail Summary Sheet

Prot No: 26H88	Status: Ongoing
TITLE: Vancomycin Dosing Based on Individual Pharmacokinetic Profiles in Neonates	
Principal Investigator: MAJ Robert V. Jarrett, MC	
Associate Investigators: MAJ Thomas J. Kueser, MC; CPT Everett L. Gayle, MC COL James W. Bass, MC	
Department/Section: Pediatrics/Neonatology Service	
Key Words: vancomycin; pharmacokinetic profiles;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Apr 88 Decision: Continue

OBJECTIVE: To determine if vancomycin dosing based on individual pharmacokinetic profiles reliably effects desired therapeutic blood levels in neonates.

TECHNICAL APPROACH: Clinical quality assurance study of blood levels to pharmacokinetic profiles.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 23H88	Status: Ongoing
TITLE: Predicting Responsiveness to Methylphenidate	
Principal Investigator: Dr. Thomas E. Gallagher, M.D.	
Associate Investigators: Dr. David S. Weiss, Ph.D.	
Department/Section: Pediatrics//Exceptional Family Member Program	
Key Words: methylphenidate(ritalin)	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Apr 88
	Decision: Continue

OBJECTIVE: To identify the variables which predict the responsiveness of Attention Deficit Disorder children to treatment with methylphenidate (Ritalin).

TECHNICAL APPROACH: Multivariant prospective data collection of patient care.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 57H88	Status: Ongoing
TITLE: Combined Utilization of Albuterol, Cromolyn Sodium and Prednisone in the Management of the Dual Phases of Acute Asthma	
Principal Investigator: CPT Wm. Joseph Horam, MC	
Associate Investigators: COL James W. Bass, MC; Dr. Wallace J. Matthews, M.D. CPT Mark E. Alexander, MC	
Department/Section: Pediatrics	
Key Words: acute asthma;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88 Decision: Continue

OBJECTIVE: To determine the clinical effectiveness of combining albuterol, cromolyn sodium and prednisone for the outpatient management of the early and late phases of acute asthma.

TECHNICAL APPROACH: Prospective clinical quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period:

New start.

Detail Summary Sheet

Prot No: 13H86	Status: Terminated
TITLE: Calcium and Phosphorus Balance Studies in Low-Birth-Weight Infants Receiving Parenteral Alimentation	
Principal Investigator: MAJ Thomas J. Kueser, MC	
Associate Investigators: MAJ Robert V. Jarrett, MC; COL Franklin R. Smith, MC	
Department/Section: Pediatrics/Neonatology Service	
Key Words: infants, low birth rate	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Nov 87 Decision: Terminate

OBJECTIVE: To determine the pattern of calcium and phosphorus excretion and retention in premature infants receiving daily calcium and phosphorus by parenteral hyperalimentation.

TECHNICAL APPROACH: All infants will receive the standard regimen of hyperalimentation which provides calcium gluceptate and sodium phosphate, in addition to maintenance sodium chloride and potassium chloride. All infants will receive the recommended daily dose of Vitamin D. In addition, 24-hour urine collections for calcium, phosphate, sodium, and creatinine excretion will be obtained in 8-hour fractions (this is the only deviation from routine NICU procedure required in this study). Calcium and phosphorus accretion rates will be compared to the standard in utero accretion rates published in medical literature.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Protocol originally developed by Dr. Stephen Pratt, who has PCS'd and no one else has actively taken on the protocol. Suggest cancellation of the protocol.

Detail Summary Sheet

Prot No: 21H86	Status: Ongoing
TITLE: Prophylactic Intravenous Sandoglobulin for Infections in High-Risk Neonates	
Principal Investigator: MAJ Thomas J. Kueser, MC	
Associate Investigators: MAJ Robert Jarrett, MC	
Department/Section: Pediatric/Neonatology Service	
Key Words: neonatal infection	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Dec 87
Gifts: Sandoglobulin	Decision: Continue

OBJECTIVE: To determine in a double-blind manner if the prophylactic use of intravenous immune serum globulin compared to an albumin placebo affects the morbidity or mortality of bacterial infections in high-risk neonates.

TECHNICAL APPROACH: Fifty consecutive infants meeting criteria for the protocol will be enrolled. The enrolled infants will receive a single IV infusion of either Sandoglobulin, 500 mg/kg, or placebo (albumin, 5 mg/kg). All infants will be monitored during infusion. Infants will be reevaluated on days 9 (postinfusion), 7, 14, and 56 with serum total IgG, opsonic antibody to GBS, physical examination, and documentation of coexisting disease, concomitant medications, antibiotic therapy, blood product transfusions, and the occurrence of septic episodes. Following the eight-week study period, blood collected for immunoelectrophoresis and historical data will be forwarded to WRAIR for evaluation.

PROGRESS: No. of Subjects Enrolled - To Date: 37 Reporting Period: 37

37 patients have been enrolled at TAMC. Over 500 patients have been enrolled overall in this multi-collaborative study. No patients have been dropped or withdrawn from the the study. The multi-collaborative study should be completed soon.

Detail Summary Sheet

Prot No: 22H86	Status: Terminated
TITLE: The Assessment of Pulmonary Function in Neonates with Severe Respiratory Distress Given Infusions of Intravenous Immunoglobulin for Suspected Sepsis	
Principal Investigator: MAJ Thomas J. Kueser, MC Associate Investigators:	
Department/Section: Pediatrics/Neonatology	
Key Words: neonates; pulmonary function; sepsis	
Funding: FY 87: NA FY 88: NA	Periodic Review Date: Dec 87
Gifts: Sandoglobulin	Decision: Terminate

OBJECTIVE: To determine in a controlled, double-blind manner if there are any changes in pulmonary function in neonates with severe respiratory distress after intravenous infusions of immunoglobulin for suspected sepsis.

TECHNICAL APPROACH: Fifty infants meeting the protocol criteria will be enrolled. Infants will receive a blinded administration of either intravenous immunoglobulin or albumin placebo. Ventilator support will be provided as indicated. Specific pulmonary functions will be monitored. Assessment of pulmonary function will be made prior to the intravenous infusion and 15 minutes, 1 hour, and 2 hours after the infusion, and the changes will be noted. The data obtained will be evaluated for possible correlation between intravenous immunoglobulin therapy and changes in pulmonary function by standard statistical methods.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No patients have been enrolled since the initial proposal. Recommend the study protocol be terminated.

Detail Summary Sheet

Prot No: 36H87	Status: Ongoing
TITLE: Identification of the Socially Isolated, Non-delinquent Youth	
Principal Investigator: MAJ Robert M. Lehman, MC	
Associate Investigators: 2LT Helene Jo, RN, ANC(Res)	
Department/Section: Pediatrics/Adolescent Medicine Service	
Key Words: adolescents, self-esteem	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Sep 88
	Decision: Continue

OBJECTIVE: To identify a subgroup of youth that are excluded by their peers and to determine if a difference in perceived self-esteem exists between peer-included and peer-excluded groups.

TECHNICAL APPROACH: All patients coming to the adolescent clinic for school physicals are asked if they desire participation. Informed consent obtained. Physicals performed, then patient placed in private room to complete questionnaires. Parents complete their form and place in the box in the waiting room.

PROGRESS: No. of Subjects Enrolled - To Date: 140 Reporting Period: 140

140 subjects have completed questionnaire; 2 parents forms not obtained, rest completed. Preliminary analyses of criteria to identify subgroup have shown some who fulfill 6 of 7 criteria but none with 7 of 7 out of 1st 50 checked. Preliminary analysis of self-concept surveys have revealed no patients with serious suicidal or self-destructive characteristics in need of acute intervention. We are trying for 300 participants to get enough to perform statistics. Several families have been intrigued by the survey. Several have not enrolled because they do not wish to spend the extra 20-30 minutes here. Of those participating, none have had any complaints.

Detail Summary Sheet

Prot No: 43H87

Status: Terminated

TITLE: Antidiuretic Hormone Secretion in the Cerebrospinal Fluid in Neonates and Children During Conditions of Infection, Hypoxia and Asphyxia

Principal Investigator: MAJ Thomas A. Perkins, MC

Associate Investigators: Venkatarman Balaraman, MD

Department/Section: Pediatrics

Key Words: antidiuretic hormone secretion

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Oct 87

Gifts: None

Decision: Terminate

OBJECTIVE: The characterization of antidiuretic hormone secretion (ADH) in the cerebrospinal fluid of neonates and children undergoing evaluation for meningitis, as a possible marker for the response of the patient's central nervous system to physiologic insult.

TECHNICAL APPROACH: CSF for ADH is collected at the time of lumbar puncture for clinical reasons. ADH levels on CSF are performed using RIA, calibrated against a curve with known standard.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 4

Four subjects have been enrolled to date. Study has been terminated upon advice from medical monitor, COL Bass. He feels that requesting additional CSF from patients undergoing lumbar puncture is an unreasonable request and requested that CSF be used after routine studies are accomplished. The ADH in such CSF has been metabolized and makes the specimen worthless.

Detail Summary Sheet

Prot No: 15A88

Status: Ongoing

TITLE: Inspiratory Flow as a Determinant of Barotrauma in New Zealand White Rabbits Rendered Surfactant Deficient

Principal Investigator: MAJ Thomas A. Perkins, MC

Associate Investigators: COL Franklin R. Smith, MC; MAJ Larry J. Godfrey, MC;
COL Robert B. Hill, MC.

Department/Section: Pediatrics/Newborn Medicine Service

Key Words: surfactant deficient

Funding: FY 87: NA FY 88: \$6,417.
Gifts:

Periodic Review Date: Jan 88
Decision: Continue

OBJECTIVE: To determine the role of inspiratory flow (Vin) in the development of ventilator induced lung damage to include air leak (Pulmonary Interstitial Emphysema - PIE) and chronic lung disease (Bronchopulmonary Dysplasia- BPD).

TECHNICAL APPROACH: Rabbits are initially sedated with IM ketamine and xylazine. Catheters, arterial and venous are placed under local anesthesia with 1% lidocaine. Endotracheal tube is placed by tracheostomy. ABG and hct performed under baseline conditions. FiO2 is increased to 1.0. After 30 min of 100% oxygen and CPAP of 4cm H2O pressure, lavage with warmed saline begins, using 20 to 30 ml aliquots. ABG is checked after every other lavage. PaO2 is reduced to 90 mm Hg. Ventilation studies begin.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Seventeen rabbits have been studied and fifteen of these were reported in presentation presented to Military Medical Pulmonary Research Review and Analysis on 22 September 1988. Currently investigation is underway using the Emerson Oscillator and the Infant Star high frequency ventilators. It is anticipated that at least 20 more rabbits will be used in this study. This study is ongoing.

Detail Summary Sheet

Prot No: 2A88	Status: Ongoing
TITLE: The Use of Hyaluronidase in the Treatment of Intravenous Extravasation Injuries	
Principal Investigator: CPT William V. Raszka, MC	
Associate Investigators: MAJ Thomas K. Kueser, MC, COL Franklin R. Smith, MC COL James W. Bass, MC	
Department/Section: Pediatrics	
Key Words: hyaluronidase; intravenous extravasation injuries	
Funding: FY 87: NA	FY 88: \$1,440.
Gifts: None	Periodic Review Date: Nov 87 Decision: Continue

OBJECTIVE: The objective of this blinded pilot study will be to determine if hyaluronidase is effective in reducing the morbidity associated with intravenous extravasation injuries. If hyaluronidase is shown to be effective, we will then determine the maximal time between extravasation of a noxious substance and effective treatment with hyaluronidase.

TECHNICAL APPROACH: CaCl_2 in a concentration determined from a pilot phase to reliably produce a full thickness skin necrosis, will be injected subcutaneously at 36 sites in 6 juvenile pigs. In a blinded manner either 150 units of hyaluronidase or 1.0cc of normal saline will be circumferentially injected subcutaneously about the injection site. The injection site will be graded by area of induration and area of necrosis to see if hyaluronidase is effective in preventing ulcer formation and skin sloughing.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

30 juvenile pigs have been used in the study so far. The study is complete with the following results: a) 300 mg/L of CaCl_2 in 2.0 cc volume injected sub-dermally will reliably create an ulcer in a juvenile pig (97/102 injections). b) Hyaluronidase in itself does not cause ulcer formation (0/18). c) Saline itself injected subcutaneously does not cause an ulcer (0/30). d) Hyaluronidase when injected circumferentially immediately following an injection of CaCl_2 will not prevent ulcer formations (48/48). e) Hyaluronidase when injected circumferentially immediately following an injection of CaCl_2 will decrease the area of ulcer formation ($p < .001$).

Detail Summary Sheet

Prot No: 33H87

Status: Ongoing

TITLE: Ceftriaxone vs. Augmentin for Initial Empirical Therapy of Occult Bacteremia

Principal Investigator: MAJ Robert R. Wittler, MC

Associate Investigators: COL James W. Bass, MC

Department/Section: Pediatrics

Key Words: occult bacteremia

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Sep 88

Gifts: None

Decision: Continue

OBJECTIVE: To evaluate the efficacy of a single intramuscular injection of ceftriaxone (75 mg/kg) versus augmentin suspension administered three times a day (40 mg/kg/day divided into three equal doses) in preventing or alleviating the acute infectious morbidity of occult bacteremia in febrile children.

TECHNICAL APPROACH: Children 3-36 months of age with documented rectal or tympanic temperature ≥ 103.0 and no source of infection by physical exam, chest x-ray, and lab (urinalysis) with informed consent will be randomized to receive empirical therapy of either oral Augmentin or one injection of IM Ceftriaxone. Patients are then followed up in 12-36 hours for evidence of focal infection and blood culture results.

PROGRESS: No. of Subjects Enrolled - To Date: 71 Reporting Period: 71

71 patients have been enrolled as of 22 July 1988. This study is going well and it will be carried on at TAMC after I leave by Dr. Baugh and Dr. Bass of the Pediatrics Department.

Detail Summary Sheet

Prot No: 42H87	Status: Completed
TITLE: Susceptibility and Tolerance of Group A β -Hemolytic Streptococcal Isolates to Penicillin and Erythromycin	
Principal Investigator: MAJ Robert R. Wittler, MC	
Associate Investigators: Steve Yamada, CPT Randy Hamill, DC,	
Department/Section: Pediatrics	
Key Words: Group A β -Hemolytic Streptococcal	
Funding: FY 87: NA	FY 88: \$1,700.
Gifts: None	Periodic Review Date: Jan 88
	Decision: Completed

OBJECTIVE: To evaluate the prevalence of in vitro tolerance and resistance of Group A β -Hemolytic Streptococcal Isolates to Penicillin and Erythromycin.

TECHNICAL APPROACH: Following NCCLS guidelines MICs for Erythromycin and Penicillin will be done on isolates of GABHS. MBCs for penicillin will also be performed to check for tolerance.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Erythromycin MICs and penicillin MICs and MDCs were completed on 300 isolates. the data is complete as of 22 July 1988.

Detail Summary Sheet

Prot No: 59A88	Status: Ongoing
TITLE: Resistance of <u>Aedes albopictus</u> in Hawaii to Mosquito Adulticides	
Principal Investigator: LTC Bruce M. Furlow, MS	
Associate Investigators: Mr. Brian Zeichner, U.S. Army Environmental Hygiene Agency (USAEHA), Aberdeen Proving Ground, MD.	
Department/Section: Preventive Medicine Service	
Key Words: mosquito; pesticides; <u>Aedes albopictus</u> ;	
Funding: FY 87: NA	FY 88: NA
Gifts: None	Periodic Review Date: Sep 88
	Decision: Continue

OBJECTIVE: Determine the mortality response of Aedes albopictus mosquito populations to pesticides commonly used in Hawaii.

TECHNICAL APPROACH: Laboratory rat will be anesthetized, hair clipped from a 2" by 5" area of the back, and the animal will be placed in a net sling over a mosquito colony. Hungry, host-seeking female mosquitoes will take a blood meal. The rat will be exposed to mosquitoes until they are satiated and no more mosquitoes are observed feeding up to a maximum of 60 minutes. The rat will be removed and euthanized. The mosquitoes will be provided time for incubation of eggs and appropriate site for deposition of eggs.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

New start.

Detail Summary Sheet

Prot No: 8H88	Status: Ongoing
TITLE: Measles Susceptibility in Hospital Personnel	
Principal Investigator: MAJ Lorrin Pang, MC	
Associate Investigators: COL Joel Brown, MC, MAJ Lawton Seal, MC MAJ Merle Sprague, MC, MAJ Philip Bruno, MC	
Department/Section: Preventive Medicine Service	
Key Words: measles;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jan 88 Decision: Continue

OBJECTIVE: Determine adequacy of ACIP screening (historical) procedure for determination of measles immunity in hospital staff. Also, prevalence of measles immunity in hospital staff will be determined.

TECHNICAL APPROACH: ACIP screening questionnaires are given to newly hired hospital staff. A sensitive and specific ELISA test for measles antibody is simultaneously done on a serum sample to determine accuracy of ACIP criteria.

PROGRESS: No. of Subjects Enrolled - To Date: 45 Reporting Period: 45

We had difficulty obtaining a sensitive specific ELISA test. This newly developed test has just been approved by the CDC and is being done, upon our recommendation, by TAMC's contract laboratory ARUP.

Detail Summary Sheet

Prot No: 51H88

Status: Ongoing

TITLE: Leptospirosis Presenting as Aseptic Meningitis

Principal Investigator: MAJ Lorrin W. Pang, MC

Associate Investigators: CPT Douglas W. Dothager, MC; COL Joel Brown, MC;
Patrick Moore, EIS Officer, CDC

Department/Section: Preventive Medicine Service

Key Words: Leptospirosis; aseptic meningitis;

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Aug 88

Gifts: None

Decision: Continue

OBJECTIVE: The purpose of this study is to examine, retrospectively, the occurrence of leptospirosis among patients given the diagnosis of "aseptic meningitis".

TECHNICAL APPROACH: TAMC records were screened retrospectively for the diagnosis of "aseptic meningitis," for the previous 18 months. Patients are asked to enroll and a serum sample is drawn for microagglutination test of leptospirosis antibody by the CDC. If prevalence of antibody is high, controls will be matched and serum tested for comparison.

PROGRESS: No. of Subjects Enrolled - To Date: 10 Reporting Period: 10

Approximately 40 cases identified by record review to date (total); 10 cases have been enrolled and serum drawn. We will continue to contact cases for enrollment.

Detail Summary Sheet

Prot No: 53H88	Status: Ongoing
TITLE: A Comparison of Brief Group Therapies for Preschool Children: Parent Training vs Group Play Therapy vs Project Group	
Principal Investigator: CPT William S. Evans, Jr., MC; Associate Investigators: CPT Susan A. Black, MC	
Department/Section: Psychiatry	
Key Words: parental training;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88 Decision: Continue

OBJECTIVE: To compare the relative efficacy of parent training, group play therapy vs project group for preschool children (4-6 years of age).

TECHNICAL APPROACH: A comparison of three short-term group therapy approaches to preschool children. Achonbach, Home Situation Questionnaire and Connors will be used as experimental measures. Three children matched for social competence will be assigned to each group which will be conducted for eight weeks, 75 minutes per week. At the end of the study and at three months, readministration of experimental measures for comparison.

PROGRESS: No. of Subjects Enrolled - To Date: 12 Reporting Period: 12

Study approved to begin August 1988. At present, collecting subjects. 12 are presently enrolled with target of 24 subjects. Starting date the first week of October. Considerable difficulties to date getting materials needed for the study secondary to inability to order research supplies after 15 July in the fiscal year.

Detail Summary Sheet

Prot No: 24H87

Status: Terminate

TITLE: Insomniac Alcoholics: Evaluation of Tryptophan Therapy

Principal Investigator: CPT Kevin J. Took, MC

(Formerly: Dr. Richard Chung, M.D.)

Associate Investigators: James Hall, PhD; LTC Terry Schultz, MC;

Department/Section: Psychiatry

Key Words: insomniac alcoholics; tryptophan

Funding: FY 87: NA FY 88: NA

Periodic Review Date: Apr 88

Gifts: L-tryptophan and placebo

Decision: Terminate

OBJECTIVE: To investigate the effect of l-tryptophan on the complaints of sleep disturbances in recovering alcoholics who are undergoing alcohol rehabilitation in a structured 6-week inpatient program.

TECHNICAL APPROACH: This study utilizes a double-blind, placebo controlled, parallel groups design. The subjects will be patients enrolled in the VA/TRISARF program who complain of insomnia and who meet inclusion/exclusion criteria. Their sleep will be evaluated by morning sleep questionnaires that assess their sleep at night as well as daytime sleepiness. All participants will have polysomnography on three nights for the diagnosis of sleep disorders other than insomnia due to alcoholism and to give objective evidence for changes in sleep architecture.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Due to the loss of the Veterans Administration funding, the new principal investigator requests that this protocol be terminated.

Detail Summary Sheet

Prot No: 20H87	Status: Terminated
TITLE: The Effect of Verapamil on Tardive Dyskinesia	
Principal Investigator: CPT Timothy J. Kowalski, D.O.	
Associate Investigators: Richard A. Markoff, M.D., Thomas F. Ditzler, Ph.D. Richard Pullen, D.O.	
Department/Section: Psychiatry	
Key Words: Verapamil, Tardive Dyskinesia	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Feb 88 Decision: Terminate

OBJECTIVE: To determine the effectiveness of verapamil in relieving or significantly decreasing the abnormal involuntary movements of tardive dyskinesia (TD).

TECHNICAL APPROACH: Double blind, placebo controlled, cross over study.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

DOD IG Audit of research project showed inappropriate solicitation of placebo by the previous Chief, DCI. Placebo was never obtained and momentum for the project has declined. Project will be terminated at the present time. The material is available to other interested people should they wish to continue this research. No subjects were ever enrolled in the study. I will be directing my research to publishing case studies and a literature review of Calcium Channel Blockers in Neuropsychiatry.

Detail Summary Sheet

Prot No: 39H87	Status: Completed
TITLE: The Recognition and Expression of Emotions by Depressed Children	
Principal Investigator: COL Richard L. Schneider, MC	
Associate Investigators:	
Department/Section: Psychiatry	
Key Words: depressed children	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Sep 88
	Decision: Completed

OBJECTIVE: To find out if depressed children show any consistent impairment in their performance of tasks requiring recognition and expression of discrete emotions.

TECHNICAL APPROACH: Children's Depression Inventory was given to each child, after which he/she was exposed to 5 facial and 5 vocal discrete affect expressions and then was taped attempting to reproduce these same 10 affects.

PROGRESS: No. of Subjects Enrolled - To Date: 51 Reporting Period: 51

No statistically significant differences were found in depressed children's ability to either recognize or express discrete affects either vocally or facially.

Detail Summary Sheet

Prot No: 41H87	Status: Completed
TITLE: Pilot Study: Treatment Outcome in Short Term Combined Behavioral and Psychoanalytic Group Therapy for Eating Disorders	
Principal Investigator: CPT Kevin Took, MC	
Associate Investigators: CPT John Forbes, MC	
Department/Section: Psychiatry	
Key Words: eating disorders	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Oct 88
	Decision: Completed

OBJECTIVE: To investigate the clinical effectiveness of a short term combination behavioral and psychodynamic out-patient eating disorders group.

TECHNICAL APPROACH: This investigation is a longitudinal study of patients enrolled in an eating disorders group at the TAMC Psychiatric Clinic at Ft. Shafter. Subjects had a diagnosis of an eating disorder (anorexia Nervosa, Bulimia Nervosa, or Eating Disorder Not Otherwise Specified) according to DSM III-R criteria. The group combined behavioral and psychoanalytic techniques and met weekly from Oct 87 - Jun 88. Subjects were weighed weekly and completed baseline and bimonthly questionnaires to include the Eating Disorders Inventory, the Beck Depression Scale, and the Ten Item Eating Disorders Questionnaire.

PROGRESS: No. of Subjects Enrolled - To Date: 11 Reporting Period: 11

The study has been completed. We are now beginning to organize the data.

Detail Summary Sheet

Prot No: 31H88	Status: Ongoing
TITLE: Stimulant Drug Response in Attention Deficit Disordered Preschoolers	
Principal Investigator: Dr. David S. Weiss, Ph.D.	
Associate Investigators: Dr. Thomas E. Gallagher, M.D.	
Department/Section: Psychiatry	
Key Words: attention deficit disorder; Ritalin;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88
	Decision: Continue

OBJECTIVE: To determine the efficacy and side-effects of Ritalin (methylphenidate) and Dexedrine (dextroamphetamine) with preschool children (3-5 years of age) diagnosed as having an Attention Deficit Disorder.

TECHNICAL APPROACH: Children diagnosed with Attention Deficit Disorder, aged 3-5 years, will be given Ritalin, Dexedrine, and placebo in a counter-balanced, double-blind, crossover design (3 weeks in each condition). Ratings will be obtained from parents as well as direct tests of attention and impulsivity on the children, prior to entry in the study and in the last week of each condition. A side effects questionnaire will also be completed by the parents.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

No subjects have as yet begun on any medication, as school is only just beginning this year. We expect the first subjects to formally enter the study in late September 1988.

Detail Summary Sheet

Prot No: 35H88	Status: Ongoing
TITLE: Midfoot Rotational Osteotomy, A Case Report	
Principal Investigator: CPT Keith S. Albertson, MC	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: osteotomy;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88
	Decision: Continue

OBJECTIVE: Present a case of a patient who had bilateral complete tarsal and metatarsal fusions at age 16 from juvenile rheumatoid arthritis. These spontaneous fusions left both her feet in supination, such that she walked on the lateral aspects of both feet. This resulted in large painful callouses along the entire lateral plantar surface. In an effort to provide the patient with plantargrade feet, osteotomies were performed through the tarsal fusion masses, and then the forefoot rotated about this osteotomy to correct the supination. The method of pre-operative evaluation, surgical approach and technique, and follow-up care will be described.

TECHNICAL APPROACH: Present the case, along with a review of corrective osteotomies of the foot. Collect pertinent information from the patient. Plan routine follow-up with X-Rays as for any other osteotomy patient, including follow-up exams at 6 weeks and six months post procedure. Include actual photographs of patient's feet if consent is given.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Study completed and written up.

Detail Summary Sheet

Prot No: 36H88	Status: Ongoing
TITLE: Volar Carpal-Metacarpal Dislocation in an Athlete. A Case Report and Review of the Literature	
Principal Investigator: CPT Keith S. Albertson, MC	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: volar carpal-metacarpal dislocation;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88
	Decision: Continue

OBJECTIVE: Present a case with an unusual mechanism for this rare injury, describe a method of treatment which allowed early resumption of athletic activity, and review the literature concerning volar carpal-metacarpal dislocations.

TECHNICAL APPROACH: Describe the mechanism of injury, appearance of the injured limb, method of reduction and closed treatment. Include description of clinical course. X-Ray and physical examinations to be conducted as per routine fracture follow-up, and again at 6 months to determine status after treatment. No additional procedures are required. Photographs may be taken with patient's consent and release. No invasive procedures are planned.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Case report awaiting follow-up.

Detail Summary Sheet

Prot No: 19H87

Status Ongoing

TITLE: Peritonsillar Abscess: Treatment with Needle Aspiration and Oral Antibiotics vs. Incision and Drainage and IV Antibiotics

Principal Investigator: LTC Gregory A. Antoine, MC

Associate Investigators: MAJ Mark H. Raterink, MC; CPT Alfred O. Park, MC;
CPT Michael P. Martin, MC; CPT Chip Kava, MC;
CPT Richard D. Kopke, MC

Department/Section: Surgery/Otolaryngology Service

Key Words: Peritonsillar Abscess

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Apr 88

Gifts: None

Decision: Continue

OBJECTIVE: To establish an effective treatment regimen for peritonsillar abscess which can be utilized by non-otolaryngologists and paraprofessional personnel in a military field setting.

TECHNICAL APPROACH: The peritonsillar area is aspirated three times with a syringe and 18 gauge needle, if pus is found they are enrolled (offered enrollment) in the study.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

There have been fewer participants than we expected. This has been because several staff have changed their minds on several occasions about whether they would allow their patients to participate. We anticipate that least another year will be necessary to reach our goal numerically. We are all in agreement about the project now. MAJ Raterink will take over as the principal investigator when I leave this summer.

Detail Summary Sheet

Prot No: 32H83

Status: Ongoing

TITLE: Prospective Study of the Use of Urinary D-Lactate Levels in Evaluation of the Acute Abdomen

Principal Investigator: COL Peter J. Barcia, MC

Associate Investigators: CPT Susan D. Leshner, MC

Department/Section: Surgery/General Surgery

Key Words: urinary D-lactate; acute abdomen

Funding: FY 87: NA FY 88: \$800.

Periodic Review Date: Feb 88

Gifts: None

Decision: Continue

OBJECTIVE: To determine the usefulness of urinary D-lactate levels in the evaluation of the acute abdomen.

TECHNICAL APPROACH: Patients evaluated for acute abdominal pain will have urinary D-lactate and creatinine specimens collected every 12 hours from the initial evaluation until four collections postoperatively or it is determined the patient does not have an acute abdomen. In addition, ten preoperatively to serve as controls.

PROGRESS: No. of Subjects Enrolled - To Date: 65 Reporting Period: 1

Experience with first 65 patients concludes that urinary D-lactate is a good diagnostic indicator of conditions of intestinal ischemia and that high levels are completely specific for significant intestinal and pancreatic necrosis.

Detail Summary Sheet

Prot No: 31H87

Status: Ongoing

TITLE: The Physiologic Response of Antidiuretic Hormone (ADH) and Human Atrial Natriuretic Factor (hANF) to Hypotonic Volume Expansion Secondary to Sorbitol Bladder Irrigation During Transurethral Prostatectomy (TURP)

Principal Investigator: CPT Paul M. Desmond, MC

Associate Investigators: MAJ L. Harrison Hassell, MC, LTC Gary Wikert, MC
John R. Claybaugh, Ph.D.

Department/Section: Surgery/Urology Service

Key Words: antidiuretic hormone; human atrial natriuretic factor

Funding: FY 87: NA

FY 88: \$2,489.

Periodic Review Date: Jul 88

Gifts:

Decision: Continue

OBJECTIVE: To assess the effect of hypotonic volume expansion, secondary to absorbed sorbitol, during TURP on ADH, hANF, renin, aldosterone and fluid and electrolytes. Both uncomplicated TURP procedures and those associated with TUR syndrome (Transurethral Resection Syndrome) will be evaluated. To postulate the roles of ADH, hANF, renin and aldosterone in the pathophysiology of the TUR syndrome in order to: 1) predict which patients are susceptible 2) propose methods during TURP for the avoidance of the syndrome in susceptible patients and 3) provide greater understanding of the pathophysiology of the TUR syndrome so it can be appropriately treated when it occurs.

TECHNICAL APPROACH: Venipuncture; multiple blood samples, weights

PROGRESS: No. of Subjects Enrolled - To Date: 15 Reporting Period: 15

15 patients evaluated. The effect of TURP and spinal anesthesia on various hormones is being evaluated. ADH appears to increase in TUR syndrome.
Adverse effects: None

Subjects Dropped/Withdrawn: 0

Ongoing study - 15 subjects enrolled to date.

Detail Summary Sheet

Prot No: 32H87

Status: Ongoing

TITLE: TAMC Protocol No. 32H87: Treatment of Ununited Fractures of Long and Short Bones with Physio-Stim Pulsed Electromagnetic Field Therapy System

Principal Investigator: COL Michael J. Fay, MC
(formerly: MAJ Thomas G. Fry, MC)

Associate Investigators: CPT J. David Pitcher, MC

Department/Section: Orthopedic Service/Surgery

Key Words: Physio-stim; ununited fractures

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: Sep 88

Gifts: None

Decision: Continue

OBJECTIVE: To make available this treatment approach to our patients pending FDA approval. To add to existing information on the safety and efficiency of the PHYSIO-STIM Pulsed Electromagnetic Field Therapy System.

TECHNICAL APPROACH: Patients are selected as eligible for the study in that they have no evidence of fracture healing within four months and have not had surgical intervention in the previous three months.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 4

There is one active participant in TAMC in this multi-center study. Of the original three initially signed up for the study, patient number one received surgery in Japan and no longer qualifies for inclusion in the study. Patient number two has recently PCS'd, is receiving surgical care at Portsmouth Naval Hospital and is also being deleted from the study as no longer eligible. The entry and projected completion dates for the all original participants is listed below. 1. Entry: 3-31-88. Lost to follow up. Surgery in Japan in May. Removed from study. 2. Entry: 3-31-88: PCS'd, Surgery at Portsmouth Naval Hospital, August 1988. Removed from study. 3. Entry: 4-19-88. Completion: 10-15-88. There have been no adverse effects to date. Of interest is that TAMC was the first of the centers involved in the study to begin, and has the highest number of participants to date.

Detail Summary Sheet

Prot No: 25H88	Status: Ongoing
TITLE: The Quadriceps to Hamstring Ratio	
Principal Investigator: COL Michael J. Fay, MC	
Associate Investigators: CPT Charles R. Scoville, SP; SFC Richard W. Weeks; 1LT Leanne M. Pentland, SP; CPT Robbin Rowell, SP.	
Department/Section: Surgery/Orthopedic Service	
Key Words: quadriceps; hamstring ratio;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Apr 88 Decision: Continue

OBJECTIVE: The purpose of this study is to determine the normal values for concentric and eccentric quadriceps to hamstring strength ratios in an athletic population, with normal knees, between the ages of 17 and 35.

TECHNICAL APPROACH: This study will use infantrymen and assorted support troops from the 25th Infantry Division (Light). We expect that approximately 200 subjects will be tested. We will collect measurements including body type, height, weight, and thigh girths. The subjects will undergo a brief orientation on the purpose of the study and the equipment used. They will then be tested on the Kin-Com. The Kin-Com is a computer driven, hydraulic resisted device, allowing dynamic torsional forces to be recorded at set velocities throughout a pre-selected range of motion using both concentric and eccentric muscular contractions.

PROGRESS: No. of Subjects Enrolled - To Date: 8 Reporting Period: 8

Lack of cooperation from the 25ID(L) in obtaining soldiers. Division wants us to come there, we cannot move the equipment without major expense and recalibration. Negotiations continue.

Detail Summary Sheet

Prot No: 16A86	Status: Completed
TITLE: Use of EEA Autosuture Device for Abdominoperineal Pull-Through Procedure for Hirschsprung's Disease	
Principal Investigator: LTC Y. C. Huang, MC Associate Investigators:	
Department/Section: Surgery/General Surgery	
Key Words: Hirschsprung's disease	
Funding: FY 87: NA FY 88: NA	Periodic Review Date: Sep 88
Gifts: EEA-type autosutures	Decision: Completed

OBJECTIVE: To study the feasibility and functional result of using an EEA autosuture device to perform colonostomy during abdominoperineal pull-through operation for Hirschsprung's disease (Swenson's and Soave's procedure).

TECHNICAL APPROACH: Using an abdominoperineal approach, the distal descending colon will be anastomosed to the anus by means of an EEA autosuture device. A 10 cm segment of the distal colon will be resected to simulate the resection of unhealthy bowel in a person. The animal will be observed daily for three weeks for its ability to defecate and stool character. The animal will then be euthanized and the entire anastomosis area will be dissected longitudinally to examine the relation of neorectum to the sphincter muscle.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

All animals survived. Two showed stenosis on x-ray study. Dilatation was carried out under light anesthesia. All animals were sacrificed at six weeks.

Use of EEA type all to anastomotic instrument for Swenson's pull-through operation for Hirschsprung's disease is feasible, easy and uniform. Stenosis of anastomosis may require dilatation. Plan human application.

Detail Summary Sheet

Prot No: 14T85	Status: Ongoing
TITLE: Microvascular Lab-Psychomotor Skills	
Principal Investigator: MAJ Thomas G. Fry, MC (formerly: MAJ Steven V. Moore, MC)	
Associate Investigators:	
Department/Section: Surgery/Orthopedics	
Key Words: training; psychomotor skills	
Funding: FY 87: NA FY 88: NA	Periodic Review Date: Sep 88
Gifts: None	Decision: Continue

OBJECTIVE: To maintain competency in microvascular technique, including anastomosis of 1 mm rat arteries and veins.

TECHNICAL APPROACH: Rats are anesthetized with sodium pentobarbital and one femoral artery and/or vein is transected and then reanastomosed. The wound is observed daily for any complications.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Training protocol for 3-5 residents for 4-8 weeks each.

Detail Summary Sheet

Prot No: 40A87	Status: Ongoing
TITLE: Emergent Initiation of Cardiopulmonary Bypass in a Swine Model	
Principal Investigator: CW3 David L. Hahn (formerly: HOLLINGSB, Michael J.)	
Associate Investigators: LTC Greg A. Bowman, MC; MAJ Gary P. Jones, MC; SFC Sam Morgan	
Department/Section: Sugery/Thoracic Surgery Svc	
Key Words: emergent cardiopulmonary bypass	
Funding: FY 87: NA	FY 88: \$4,860.
Gifts: None	Periodic Review Date: Oct 88 Decision: Continue

OBJECTIVE: To introduce and familiarize personnel with the initiation of emergent cardiopulmonary bypass (ECPB) procedure using the swine model.

TECHNICAL APPROACH: Training protocol using terminally anesthetized swine.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA
New start.

Detail Summary Sheet

Prot No: 9H87	Status: Ongoing
TITLE: Gait Efficiency of AK Amputees; The Effects of Prosthetic Components	
Principal Investigator: CPT Richard A. Hynes, MC	
Associate Investigators: COL Michael Romash, MC; CPT Beau J. Freund, MSC; Dr. Richard Cirillo, M.D.	
Department/Section: Surgery/Orthopedic Service	
Key Words: AK Amputees; Prosthetic feet	
Funding: FY 87: NA	FY 88: \$50.
Periodic Review Date: Apr 88	
Gifts: Prosthetists' time	Decision: Continue

OBJECTIVE: (1) To determine if socket design and terminal devices, especially kinetically active terminal devices, change the efficiency of gait of above-knee (AK) amputees, and (2) to establish a scientific basis and experimental program upon which foot terminal devices can be compared using the energy expenditure of gait as a modality for comparison.

TECHNICAL APPROACH: Using treadmill to assess energy consumption.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Project ongoing - initial testing for preliminary data is being conducted on Fridays 1-2 times every month. Expected duration is 3-5 months. At test time if a significant difference can be determined by this technique, more patients will be needed and a new protocol submitted.

Detail Summary Sheet

Prot No: 20H86	Status: Terminate
TITLE: The Role of Intralesional Steroids in the Acute Care of Fractures of the Distal Radius	
Principal Investigator: CPT Richard A. Hynes, MC	
Associate Investigators: MAJ Courtenay S. Whitman, IV	
Department/Section: Surgery/Orthopedic Service	
Key Words: fractures; intralesional steroids; hematoma	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jan 88
	Decision: Terminate

OBJECTIVE: To determine the efficacy of steroid injections into the hematoma of acute wrist fractures as a means of decreasing postinjury edema, pain, and stiffness. The study will also examine any effects on healing time.

TECHNICAL APPROACH: A prospective blind study will be undertaken to evaluate the clinical effects of intralesional steroid injections.

PROGRESS: No. of Subjects Enrolled - To Date: 15 Reporting Period: 15

Fifteen (15) patients have been enlisted, however, the project has been curtailed by the principal investigator due to his absence from Tripler. Data on the patients enlisted so far is so incomplete that little valuable information can be gleaned from it.

Project is not currently active, and data on patients enlisted in study is not available. A list of patients is available, but followup data after treatment is not present. Current staff physicians do not desire to be involved with this study, as none are enthusiastic about the technique of injection of fractures with steroids.

Detail Summary Sheet

Prot No: 15T85	Status: Ongoing
TITLE: Animal Models for Advanced Trauma-Life Support Provider and Instructor Courses	
Principal Investigator: LTC Eric A. Johnson, MC (formerly: MAJ Richard G. Kilfoyle, MC)	
Associate Investigators: COL Donald W.S. Yim, MC; MAJ Frank Rogers, MS; MAJ Albert McCullen, VC	
Department/Section: Surgery/General Surgery	
Key Words: advanced trauma life support	
Funding: FY 87: NA FY 88: \$7,174.	Periodic Review Date: Oct 88
Gifts: None	Decision: Continue

OBJECTIVE: To fulfill the requirement of ATLS Provider and Instructor courses, i.e., to teach physicians a standardized approach to trauma care in the early hours of trauma patient assessment and to teach life-saving skills using animal models.

TECHNICAL APPROACH: Goats or pigs are deeply anesthetized with sodium pentobarbital and prepared for surgery. Participants then perform cricothyroidotomy, peritoneal lavage, chest tube placement, pericardiocentesis, and venous cutdown procedures under the close supervision of certified instructors. Animals are euthanatized at the end of the surgery laboratory.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

New Principal Investigator is LTC Eric A. Johnson, MC and Associate Investigator is COL Donald W.S. Yim, MC. Project should continue. Adverse effects: None.

Detail Summary Sheet

Prot No: 34H87	Status: Terminated
TITLE: Otic Pruritis in Patients with Atopic Disease	
Principal Investigator: CPT Charles F. Kava, MC	
Associate Investigators: MAJ Robert E. Bowen, MC; MAJ Larry A. Zieske, MC	
Department/Section: Surgery/Otolaryngology Service	
Key Words: otic pruritis; atopic disease	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88
	Decision: Terminate

OBJECTIVE: To determine what proportion of patients seen at TAMC who suffer from one or more of the "classic" manifestations of atopic disease (asthma, rhinitis and eczema) are troubled by pruritis in the ear canals. Next, to determine whether this symptom actually represents a manifestation of atopic disease versus an unrelated phenomenon (i.e. due to mechanical irritation or lack of cerumen).

TECHNICAL APPROACH: 2-arm study of Seldane and Duravent measured by symptom score sheets.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Protocol terminated due to lack of progress.

Detail Summary Sheet

Prot No: 44A86	Status: Terminated
TITLE: Studies on the Effects of Calcium Entry Blockers in Experimental Adult Respiratory Distress Syndrome in Sheep	
Principal Investigator: MAJ Richard G. Kilfoyle, MC (formerly: COL Samuel A. Cucinell, MC)	
Associate Investigators: Bert K.B. Lum, Ph.D.	
Department/Section: Surgery/General Surgery Service	
Key Words: calcium entry blockers; respiratory distress	
Funding: FY 87: NA	FY 88: NA
Gifts: None	Periodic Review Date: Sep 88 Decision: Terminate

OBJECTIVE: To determine if calcium entry blockers (CEBs) can prevent the pulmonary pathophysiology caused by endotoxin.

TECHNICAL APPROACH: Adult sheep will be chronically instrumented. The efferent duct of the caudal mediastinal lymph node will be cannulated for collection of pulmonary lymph. A chronic tracheostomy opening will be made for later insertion of a cuffed tracheostomy tube during experiments. A carotid loop will be created for measurement of arterial pressure and obtaining blood samples. After three weeks for surgical recovery, small (nonlethal) doses of endotoxin will be administered. Measurements will include lymph flow, lymph protein concentration, ratio of lymph to plasma protein concentration as indices of pulmonary permeability, dynamic compliance, airway resistance, cardiac output, heart rate, total peripheral resistance, arterial blood gases, and lung lymph thromboxane, prostacyclin, serum fibrin degradation products, and pulmonary clearances of platelets and white blood cells.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

This protocol has been inactive due to the departure of the original principal investigator. The new Principal Investigator, MAJ Richard G. Kilfoyle, MC, Department of Surgery was assigned on 16 Sep 87. Discontinued by General Surgery Service since Dr. Kilfoyle has departed TAMC.

Detail Summary Sheet

Prot No: 2T84	Status: Terminated
TITLE: Training Protocol for Microsurgery	
Principal Investigator: MAJ Stuart B. Kincaid, MC	
Associate Investigators:	
Department/Section: Surgery/Plastic Surgery	
Key Words: training; microsurgery	
Funding: FY 87: NA FY 88: NA	Periodic Review Date: Sep 88
Gifts: None	Decision: Terminate

OBJECTIVE: To develop and maintain proficiency in microvascular anastomosis of veins, arteries, and nerves.

TECHNICAL APPROACH: The groin vessels of the rat or rabbit will be transected and reanastomosed using microvascular principles. The ears of the rabbit will be transected near its junction with the scalp and replantation attempted through microvascular techniques.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Principal investigator has PCS'd and department requested termination of the protocol.

Detail Summary Sheet

Prot No: 23H86	Status: Terminated
TITLE: Comparison of Open Surgical and Transvenous Interruption of Varicocele in Infertile Males	
Principal Investigator: CPT Karl J. Kreder, MC	
Associate Investigators: COL Martin Dresner, MC; LTC William G. Kennon, MC; MAJ Jean Laberge, MC; CPT Marc Pliskin, MC; CPT Paul Desmond, MC	
Department/Section: Surgery/Urology Service	
Key Words: varicocele; male fertility	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88 Decision: Terminate

OBJECTIVE: This is a randomized, prospective, controlled, comparative trial of two standard approaches for the treatment of varicocele, presumed to cause infertility.

TECHNICAL APPROACH: One hundred patients with infertility and otherwise healthy, on no medication, with a varicocele, normal hormonal studies, and abnormal SPA (less than 10%) will undergo a prospective, randomized, and controlled study. Study participants will have SPA and semen analysis at 1, 3, and 6 months and will be randomized into two groups, one undergoing inguinal ligation and the other percutaneous transvenous embolization. Both groups will have follow-up SPA and semen analysis at 3, 6, 9, and 12 months. Data collected will be used to (a) determine the success rate of percutaneous and surgical repair of varicocele, (b) determine the failure rate of both methods, (c) determine the relationship of varicocele size to success rates, (d) determine the ability of the SPA to predict successful repair, (e) correlate semen analysis results with successful varicocele repair, and (f) determine whether grading of the size of varicocele by physical examination correlates with ultrasound.

PROGRESS: No. of Subjects Enrolled - To Date: 30 Reporting Period:

The protocol is cancelled due to lack of participants.

Detail Summary Sheet

Prot No: 5A87	Status: Completed
TITLE: The Use of Treated Umbilical Vein Graft as a Tissue Substitute in the Urinary Tract of Pigs	
Principal Investigator: MAJ Karl J. Kreder, Jr., MC	
Associate Investigators: COL Martin Dresner, MC; LTC William Kennon, MC; COL Douglas Soderdahl, MC; CPT Mark Pitts, MC; MAJ Albert McCullen, VC	
Department/Section: Surgery/Urology Service	
Key Words: umbilical vein graft	
Funding: FY 87: NA	FY 88: \$904.
Gifts: none	Periodic Review Date: Nov 87 Decision: Completed

OBJECTIVE: To determine if treated umbilical vein will survive when implanted in the urinary tract.

TECHNICAL APPROACH: Six pigs have been used for Implantation of umbilical vein. The Implant was done full thickness into the anterior bladder wall as described in the original protocol. All pigs survived until sacrifice approximately 10 weeks post operatively.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Study is completed and principal investigator is currently preparing manuscript for journal publication.

Detail Summary Sheet

Prot No: 42H88	Status: Ongoing
TITLE: Treatment of Lipomatosis with Non-Steroid Anti-inflammatory (NSAI) drugs and Tamoxifen	
Principal Investigator: LTC Y-T. Margaret Lee, MC	
Associate Investigators:	
Department/Section: Surgery/General Surgery Service	
Key Words: tamoxifen; lipomatosis;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88
	Decision: Continue

OBJECTIVE: To determine if multiple lipomatosis will respond to Indomethacin, and/or Sulindac and/or Tamoxifen. (There are reports in the literature that reported that colonic polyposis and desmoid tumors did shrink with the treatment of these 3 drugs, either singularly, or in various combinations).

TECHNICAL APPROACH: Patient will be given Indomethin first for two months. If there is evidence of shrinkage, the drug will be continued. If there is no response, the drug will be stopped for a month. Then Sulindac will be tried. Tamoxifen will be the third drug to be used. All 3 drugs are included in the TAMC Formulary and conventional doses will be used.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Only one patient has been enrolled in August of 1988.

Detail Summary Sheet

Prot No: 17E78	Status: Ongoing
TITLE: Human Implantation of Intraocular Lenses	
Principal Investigator: COL Anthony P. Martyak, MC	
Associate Investigators:	
Department/Section: Surgery/Ophthalmology	
Key Words: intraocular lenses	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: May 88
Gifts: None	Decision: Continue

OBJECTIVE: To study the effects of implantation of intraocular lenses in humans.

TECHNICAL APPROACH: Utilization of posterior chamber intraocular lenses requires an extracapsular cataract method with preservation of the posterior lens capsule. Anterior chamber intraocular lenses are used after a routine intracapsular cataract extraction, as secondary implants, and when the posterior capsule is broken during an extracapsular cataract procedure.

PROGRESS: No. of Subjects Enrolled - To Date: 104 Reporting Period: 104

During the period May 1987 through April 1988, 104 intraocular lenses were implanted in patients. 11 of the lenses were anterior chamber and 93 were posterior chamber lenses. 96 of the implants were primary implants (done at the time of original surgery), and 7 were secondary implants. One non-fixated posterior lens done three years ago elsewhere was replaced because of secondary uveitis, macular edema and decreased vision. The lens exchange was uncomplicated and the patient has had improvement of both his visual function and macular edema. All the posterior and anterior chamber lenses used during this period have been removed from investigational status by the FDA. No IRC was required from these currently used lenses. However, if we should stock any of the newer designed lenses which would be in the Adjunct Study phase and considered investigational by the FDA, an IRC would be necessary. Principal investigator has PCS'd. The new principal investigator is COL J. Michael Geiger, Jr., MC.

Detail Summary Sheet

Prot No: 45H88	Status: Completed
TITLE: Effect of Posterior Instrumentation and Fusion of the Spine on Spinal Length in Idiopathic Scoliosis	
Principal Investigator: CPT Craig M. Ono, MC	
Associate Investigators: COL Kent A. Reinker, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: idiopathic scoliosis;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88
	Decision: Completed

OBJECTIVE: Study consists of a retrospective chart and radiograph review of patients who have idiopathic scoliosis and who have undergone posterior instrumentation and spinal fusion. Measurements of anterior and posterior spinal lengths are to be correlated pre- and post- operatively.

TECHNICAL APPROACH: Charts and radiographs are to be reviewed. Measurements from radiographs are to be performed using standard landmarks. Anterior and posterior spinal lengths and curve magnitudes and pre- and post- operative will be recorded.

PROGRESS: No. of Subjects Enrolled - To Date: 29 Reporting Period: 29

This project has been completed. The charts and radiographs of 29 patients have been reviewed. Data have been collated and analyses have been accomplished. The paper has been completed and is to be presented by Dr. Reinker at this year's Shriners Chiefs' meeting, 7 October 1988.

Detail Summary Sheet

Prot No: 50H85	Status: Ongoing
TITLE: Arthroscopic Evaluation of Acute Primary Shoulder Dislocations	
Principal Investigator: CPT J. David Pitcher, Jr., MC (formerly: Uribe, J.D.)	
Associate Investigator: COL Michael J. Fay, MC	
Department/Section: Surgery/Orthopedics	
Key Words: shoulder dislocation; arthroscopy	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Sep 88
Gifts: None	Decision: Continue

OBJECTIVE: To evaluate arthroscopically the lesions associated with shoulder dislocations and correlate these lesions with prognostic indicators relative to recurrent dislocations.

TECHNICAL APPROACH: Patient referral requests will be sent to all outlying clinics requesting referral of all patients with initial shoulder dislocations documented by radiographs. Patients entered into the study will be admitted to TAMC Orthopedic Service and placed on the surgery schedule. Arthroscopy will be performed as soon as possible after the injury. Intra-articular pathology will be documented on operative findings data sheets and photographs of pathology will also be maintained in the data file for each patient. Postoperatively, patients will be placed in shoulder immobilizers for three weeks, followed by physical therapy with range of motion and shoulder bridle strengthening program for four weeks. Patients will then be progressed to full duty over a four-week period, and will be followed monthly in Sports Medicine Clinic for six months to one year, documenting clinical progress. Subsequent clinical progress and recurrent dislocation will be correlated with initial pathology documented by arthroscopy.

PROGRESS: No. of Subjects Enrolled - To Date: 47 Reporting Period: 10

- 1) I have received all additional information from the previous investigators and a total of 47 patients who meet all criteria have been evaluated arthroscopically. There have been two redislocations, one in each of the groups (stapled vs not stapled). Information on patients from West Point and Hughston Clinics were not complete and that data was dropped, to account for this discrepancy in total number of patients from last year.
- 2) Other centers were to have begun similar studies and their results are being combined with TAMC's. These institutions are: West Point and Hughston Clinic. However, this has not materialized.
- 3) There have been 47 patients involved in the study to date. One surgical stapling has failed and has undergone the standard repair for re-dislocation. The new principal investigator assigned is MAJ J. David Pitcher, Jr, MC and the new associate investigator is COL Michael J. Fay, MC.
- 4) We will stop the enrollment of new patients when 3 more patients are obtained (total 50) and continue their progress for long term results. Depending on these results, determination will be made as to whether the standard care for primary shoulder dislocations is to be altered.

Detail Summary Sheet

Prot No: 23A87

Status: Completed

TITLE: The Use of Treated Umbilical Vein Graft as a Catheterizable Conduit in the Urinary Tract of Pigs

Principal Investigator: CPT Marc J. Pliskin, MC

Associate Investigators: CPT Karl J. Kreder, MC; COL Martin Dresner, MC;
COL William Kennon, MC; LTC Gary Wikert, MC;
CPT Gary Cooper, MC; MAJ Albert McCullen, VC

Department/Section: Surgery/Urology Service

Key Words: umbilical vein

Funding: FY 87: NA

FY 88: \$216.

Periodic Review Date: Jun 88

Gifts:

Decision: Completed

OBJECTIVE: To determine if treated umbilical vein will provide continent catheterizable conduit in the urinary tract.

TECHNICAL APPROACH: Treated human umbilical vein graft was used to create a conduit (catheterizable and non-leaking) from the bladder of the pig to the skin. X-rays and subsequent catheterization of the graft would be performed to determine survivability and technical success.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 4

Project completed: To be presented at Kimbrough - Government Service Urologists Meeting 30 Oct - 4 Nov 1988, Norfolk, VA. Submitted for presentation to the American Urologic Association Meeting in Dallas, May 1989. Submission for publication will follow. Pathologic analysis showed chronic and acute inflammation consistent with Xenograft reaction. This should not be a problem in a clinical setting where it would be an allograft. Also skin stenosis became problematic at 6 weeks - owing to only twice weekly catheterization - again less problematic in a clinical setting where catheterization would be done four times a day.

Detail Summary Sheet

Prot No: 7H87	Status: Ongoing
TITLE: Post-therapy Hypocalcemia in the Treatment of Patients with Hyperthyroidism	
Principal Investigator: MAJ Mark Raterink, MC	
Associate Investigators: MAJ Craig Holland, MC; MAJ Kris Raines, MC; MAJ Harrison Hassell, MC; CPT Donald Moe, MC; CPT Joel Link, MC	
Department/Section: Surgery/Otolaryngology	
Key Words: hypocalcemia, hyperthyroidism	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Nov 88 Decision: Continue

OBJECTIVE: To sort out the clinical importance of the first four following mechanisms: (1) post-treatment parathyroid deficiency, (2) thyrotoxic renal magnesium wasting, (3) thyrotoxic osteodystrophy, (4) renal hypercalciuria, and (5) other mechanisms.

TECHNICAL APPROACH: Measurement of blood Free T₄, T₃, RIA, TSH thyroid antibodies, Mg, Ca, PTH, Calcitonin and urinary routine chemistry plus Ca, PO₄, hydroxyproline and cyclic-AMP will be compared with medication dosages.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 4

Very few patients have been entered into the protocol thus far. Though there have been adequate numbers of Graves patients, most of these have not met criteria for entrance into the study (i.e. patient lives off island; one has other systemic disease).

Detail Summary Sheet

Prot No: 15A87	Status: Ongoing
TITLE: Menisci Energy-Absorbing Characteristics of Pig Hind Knee with Both Static and Dynamic Loads	
Principal Investigator: CPT Kenneth Reesor, MC	
Associate Investigators: COL Kent Reinker, MC; MAJ John Uribe, MC; Mr. W. Ichimura, Biomedical Engineering Technician	
Department/Section: Surgery/Orthopedic Service	
Key Words: meniscal injuries	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Feb 88
Gifts: None	Decision: Continue

OBJECTIVE: To establish the energy-absorbing characteristics of the pig knee and to determine if these characteristics are dependent on the percentage of meniscal intact.

TECHNICAL APPROACH: Instrumentation to apply impact loading to isolated pig knees (slaughterhouse donations) will be developed and measurements made of 1) transmitted pressures 2) compression displacements and 3) circumferential elongation or expansion of exercise.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA
Awaiting equipment fabrication.

Detail Summary Sheet

Prot No: 46A85	Status: Ongoing
TITLE: Altered Consciousness Induced by Overdrainage of Cerebrospinal Fluid	
Principal Investigator: COL Bernard Robinson, MC, USAR	
Associate Investigators: John R. Claybaugh, Ph.D.; MAJ Jon Graham, MC	
Department/Section: Surgery/Neurosurgery	
Key Words: cerebrospinal fluid	
Funding: FY 87: NA FY 88: \$99.	Periodic Review Date: Sep 88
Gifts: None	Decision: Continue

OBJECTIVE: To create an animal model in which coma can be induced by overdrainage of cerebrospinal fluid. Additionally, we hope to be able to demonstrate complete reversal of coma by replacing the volume of CSF removed. We hope to characterize any changes induced by the test maneuver (CSF drainage) in the parameters studied.

TECHNICAL APPROACH: Various parameters of vital functions are to be monitored during the investigation. These include electroencephalogram, blood pressure, electrocardiogram, and pulse rate. The test animal will require a craniectomy and insertion of a reservoir to be used for the actual access to the intrathecal compartment chosen for removal of CSF.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Required equipment has been funded and the equipment is in route.

Detail Summary Sheet

Prot No: 36E83	Status: Terminated
TITLE: The Effect of Continuous Passive Motion on Intra-articular Trauma with Continuous Passive Motion Device (CPMD)	
Principal Investigator: COL Michael M. Romash, MC	
Associate Investigators: CPT Harald J. Henningsen, MC	
Department/Section: Surgery/Orthopedic	
Key Words: intra-articular trauma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jun 88
Gifts: None	Decision: Terminate

OBJECTIVE: To assess the effect of continuous passive motion of joint function and rehabilitation after injury and/or repair of knee.

TECHNICAL APPROACH: Patients with intra-articular injuries of tibial plateau fractures, ruptured knee ligaments, reconstructed knee ligaments, patellar fractures, and dislocated patellae will be placed in the CPMD immediately after treatment. This will be done in a sequential fashion, alternating those so treated with those treated in the present fashion with early active motion or intermittent passive motion with no crossover. A total of 100 patients will be studied. The two groups will be compared regarding range of motion, need for narcotic medications, and bleeding, and will be followed for as long as possible for sequelae to their injury. If further surgery becomes indicated on the involved joint, inspection of cartilage will be accomplished. Rehabilitation parameters will also be measured, thigh girth, ability to weight-lift, and the range and timing of return to active duty or productive employment will be ascertained.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Protocol terminated for lack of progress.

Detail Summary Sheet

Prot No: 40A86	Status: Ongoing
TITLE: The Effect of Infusing Embolic Material into the Liver as an Adjunct to Liver Resection in the Pig	
Principal Investigator: CPT Council C. Rudolph, MC	
Associate Investigators: CPT Robert Thomas, MC; MAJ Jean Laberge, MC; LTC Y-T Lee, MC; CPT Everett Gale, MC	
Department/Section: Surgery/General	
Key Words: Liver resection, embolic material	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Dec 88 Decision: Continue

OBJECTIVE: To determine the efficacy of intraoperatively infusing embolic agents into the hepatic circulation prior to liver resection.

TECHNICAL APPROACH: Under general anesthesia, the left hepatic branch of the portal vein is isolated and ligated. 2-3 units of Angiostat particles are infused via the isolateral vein into the liver. The hepatic artery on the left is ligated. The left lobe of the liver is resected via finger fracture techniques. Intraop and postop parameters are measured to gauge blood loss and operative ease.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The first three pigs enrolled were sacrificed and used to gain early experience in anatomy and operative techniques. Of the five subsequent pigs, only two have lived beyond the first postop week; both were control pigs. Three of the subsequent pigs died; one from an apparent biliary injury, the second from massive gastroparesis and the third from vascular compromise of the remaining liver. Only the first two of these pigs were embolized. It is apparent that liver resection in the pig is quite a postoperative undertaking (as per Dr. Cucinell's predictions) and changes to the protocol requesting only a three-day postoperative course with euthanasia at that time have been submitted. With the experience thus far, the operation itself can safely be undertaken in under 2½ hours. The three-day postop period will allow adequate measurements of the postup course yet will not subject the pig to a difficult and prolonged postoperative period which we are not presently equipped to guide the pig through.

Detail Summary Sheet

Prot No: 49H88	Status: Ongoing
TITLE: The Changing Spacial Relationship of the Patella and Tibia in Normal Knee Motion	
Principal Investigator: CPT James L. Rungee, MC	
Associate Investigators: 2LT Thomas M. DeBerardino, MS; COL Michael J. Fay, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: normal knee motion;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To radiographically determine and document the motion of the patella in space relative to the tibia during normal knee motion.

TECHNICAL APPROACH: Ten (10) volunteers will be picked at random for radiographic evaluation of both knees. To qualify for the study, the participants must have asymptomatic knees, free of instability or other pathologic process as documented by clinical and routine radiographic examination. Lateral radiographs of each knee will be obtained at predetermined degrees of flexion (0, 30, 60, and 90 degrees) as confirmed by goniometric measurement. Using the tibial profile as reference, the spacial motion of the patella will be plotted, measuring specifically:

- a) the antero-posterior excursion of the patella, and
- b) the changing longitudinal tilt of the patella.

Diagramatic tracings as well as graphical plottings will be utilized to establish the basic characteristic and mean spacial changes of the patello-tibial relationship.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0
New start.

Detail Summary Sheet

Prot No: 52H88	Status: Ongoing
TITLE: Biomechanical Aspects of Olecranonization of the Patella	
Principal Investigator: CPT James L. Runge, MC	
Associate Investigators: COL Michael J. Fay, MC; Wayne Ichimura, Biomedical Engineer.	
Department/Section: Surgery/Orthopedic Service	
Key Words: patella;olecranonization;	
Funding: FY 87: NA	FY 88: \$800.
Gifts:	Periodic Review Date: Aug 88 Decision: Continue

OBJECTIVE: a) To study and determine whether olecranonization of the patella actually functions to relieve tension across repairs and reconstructions of the Posterior Cruciate Ligament of the knee, and b) If tension is indeed lessened, to determine the ideal position and method of pin placement that affords limited post-operative knee motion while still protecting the Posterior Cruciate Ligament repair.

TECHNICAL APPROACH: Biomechanical measurements of surgical procedure.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0
New start.

Detail Summary Sheet

Prot No: 22H85	Status: Completed
TITLE: Flow Cytometry Network for Bladder Cancer	
Principal Investigator: COL Martin L. Dresner, MC (formerly: COL Douglas W. Soderdahl, MC)	
Associate Investigators:	
Department/Section: Surgery/Urology	
Key Words: bladder cancer; flow cytometry	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: May 88
Gifts: *	Decision: Completed

OBJECTIVE: To develop a laboratory flow cytometric network to study urinary bladder cancer.

TECHNICAL APPROACH: The application of flow cytometry to the diagnosis of cancer is still being actively investigated, and the work of this project will include evaluations for sample preparation and cell dispersal, cell fixation, and different staining techniques, as well as the implications of degrees of aneuploidy. This latter would include studies to evaluate the role of various papilloma virus in bladder cancer, to establish flow cytometry as an effective screening method in following recurrent disease, and in correlating the degree of aneuploidy with histological grade and progress.

PROGRESS: No. of Subjects Enrolled - To Date: 154 Reporting Period: 142

Study is completed and was successful in decreasing "noise" of the assay and allowing more sensitive detection. Study was completed by departed investigator.

Results were presented at the Western Section of AUA, Kona, Hawaii, February 1987 and the SWOG Meeting in San Antonio, March 1987.

*Flow cytometry to be done at the Cancer Research Center of Hawaii.

Detail Summary Sheet

Prot No: 22A87

Status: Terminated

TITLE: D-lactate Excretion In Rat Model Of Ischemic And Infarcted Bowel

Principal Investigator: CPT David M. Watts, MC

Associate Investigators: COL Peter J. Barcia, MC; CPT Robert S. Thomas, MC;
CPT Randy Hammill, MC; MAJ Albert McCullen, VC

Department/Section: Surgery/General Surgery

Key Words: D-lactate ischemic and infarcted bowel

Funding: FY 87: \$3,490. FY 88: \$800.

Periodic Review Date: Feb 88

Gifts: None

Decision: Terminate

OBJECTIVE: Establish whether d-lactate is excreted in increased amounts in intestinal ischemia and infarction. A rat model of intestinal ischemia/infarction will be used.

TECHNICAL APPROACH: D-lactate is a bacterial metabolite which could potentially serve as a marker for early intestinal ischemia. This hypothesis is being investigated by measuring serum d-lactate levels in four different groups of rats. One group of animals undergoes sham surgery only (midline abdominal incision and closure). The three experimental groups undergo either permanent total ligation of the superior mesenteric artery, temporary superior mesenteric artery occlusion or ligation of a branch of the superior mesenteric artery. Serial d-lactate levels are measured to determine if d-lactate rises in relation to the degree of intestinal ischemia/infarction.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Study is terminated per General Surgery Service's request because of technical problems with the model.

Detail Summary Sheet

Prot No: 24H88

Status: Ongoing

TITLE: Water Sports Injuries in Hawaii

Principal Investigator: CPT Gregory G. West, MC

Associate Investigators: COL Michael J. Fay, MC; G. Harley Hartung, Ph.D.;
MAJ Frederick Thaler, MC.

Department/Section: Surgery/Orthopedics Service

Key Words: water sports injuries

Funding: FY 87: NA

FY 88: \$800.

Periodic Review Date: May 88

Gifts: None

Decision: Continue

OBJECTIVE: To establish a registry of information on water sports injuries in Hawaii.

TECHNICAL APPROACH: Data registry (cooperative state-wide program).

PROGRESS: No. of Subjects Enrolled - To Date: 0

Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: 28H88	Status: Ongoing
TITLE: Treatment Assessment of Multiple Plantar Warts with Acyclovir	
Principal Investigator: MAJ Barney A. Yanklowitz, MS;	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: plantar warts; acyclovir;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: May 88
	Decision: Continue

OBJECTIVE: To discover whether or not an occlusive foot dressing improves the reported results (25%, 38%, 39%) of topical 5% Acyclovir for the treatment of multiple plantar warts after 8 and then 12 weeks.

TECHNICAL APPROACH: A clinical investigation including 68 patients ages 2 to 70 (unless pregnant or nursing mother) with a clinical diagnosis of multiple plantar warts (6 or more) or a large surface area (greater than 2.54 cm. diameter) mosaic plantar warts will be treated.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Project began on 6 September 1988 due to review of statistical analysis and patient selection protocol. Patient selection/participation will be low and completion of this project will take 24 months because I only treat one or two patients/month with this severe of wart infection.

Detail Summary Sheet

Prot No: 37H88	Status: Ongoing
TITLE: Sonography of Morton's Neuromas	
Principal Investigator: MAJ Barney A. Yanklowitz, MS	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: Morton's neuromas	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To evaluate the size of the third webspace plantar nerve on sonography as a positive predictive indicator of biopsy confirmed Morton's neuromas.

TECHNICAL APPROACH: Aggressive conservative therapy for Morton's neuroma includes: examination of duty and recreational footwear; limitation or cessation of hyperextension (of MTPJ) causing activities for six weeks; the use of pedal orthoses (insoles, metatarsal pads) for six weeks; NSAID for 12 weeks; plantar intermetatarsal nerve blocks (local anesthetic and corticosteroid). After failure of aggressive conservative therapy or in the presence of a palpable mass, elective sonography of the affected webspace will be requested by a member of the Orthopedic Service. This routine sonography will be scheduled by appointment and completed by personnel assigned to the Ultrasound Section, Department of Radiology. The resultant hard copy images will be used by the attending Orthopedic staff for operative planning and patient education. Photographs of sonographs and neuromas (in situ or biopsied specimens) will be completed for no more than 48 patients. Neuromas will be confirmed by standard biopsy techniques.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Study approved on 6 September 1988. This study will take at least 18 months. No adverse effects. No patients dropped/withdrawn.

Detail Summary Sheet

Prot No: 19H83	Status: Terminated
TITLE: Phase II Study of Human Interferons- α (HuIFN- α (Le)) in Patients with Nasopharyngeal Carcinoma (NPC) and Determination of the Effect of IFN on Epstein-Barr virus (EBV)-related Immunological Markers	
Principal Investigator: COL Donald W. S. Yim	
Associate Investigators: Nathaniel Ching, M.D.; Thomas Lou, M.D.; Kevin Loh, M.D.; Meredith Pang, M.D.; Clara Ching, M.D.; Thomas Merigan, M.D.	
Department/Section: Surgery/Otolaryngology	
Key Words: Interferon- α ; nasopharyngeal carcinoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jun 88
Gifts: Interferon	Decision: Terminate

OBJECTIVE: (1) To determine the objective response rate to HuIFN- α (Le) in patients with NPC. (2) To measure time and onset and duration of response. (3) To determine changes in EBV-related immunologic markers in response to IFN. (4) To determine clinical and laboratory factors that correlate with therapeutic activity. (5) To determine the toxicity of IFN in patients with NPC.

TECHNICAL APPROACH: Approximately 20 patients will be enrolled in the study who have received at least two weeks of treatment with (HuIFN- α (Le). Approximately 10 patients will be entered from Hawaii. This Honolulu aspect of the study will be in collaboration with Dr. Thomas Merigan who is the principal investigator at Stanford University, and the interferon will be administered under his IND number for use of the investigational drug.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

Study has been terminated.

Detail Summary Sheet

Prot No: 7H88	Status: Ongoing
TITLE: Urine Detectability in Patients and Physicians of Intranasal 4% Topical Cocaine During Clinical Utilization	
Principal Investigator: MAJ Larry A. Zieske, MC	
Associate Investigators: MAJ Charles A. Moore, MS; MAJ Alfred O. Park, MC; MAJ Mark H. Raterink, MC; CPT Michael P. Martin, MC; MAJ Richard D. Kopke, MC; CPT Charles F. Kava, MC	
Department/Section: Surgery/Otolaryngology Service	
Key Words: topical cocaine;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To determine the detectability of intranasally applied 4% topical cocaine in patients and physicians, applying this in their routine clinical practice. A dose versus time post-exposure graph is to be sought. To determine the protectability of surgical gloves to the applying physician. to determine cutaneous absorption of cocaine by urine drug screening.

TECHNICAL APPROACH: To obtain base lines on each physician and patient. To sample patients urine post controlled and documented exposure to cocaine by ENT physicians. The sampling will be: First 6-8 hours post-op and then on a daily basis for 3 days (beyond the normally expected point of negative detection) after any cocaine exposure. Quantification of urine metabolite level will be done as much as possible. Physician samples will also be obtained after use of cocaine with and without latex glove use to check for glove protection and cutaneous absorption. Approximately 24 exposures will be monitored (24 patient and 24 surgeons). The analysis will be by IRA and mass spectrometry. Documenting of all medications will be done (over the counter and prescribed). Chain of custody will be maintained.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Project will be started in the early 1989 time frame.

Detail Summary Sheet

Prot No: 26D84	Status: Ongoing
TITLE: Use of Sodium Allopurinol to Control Hyperuricemia in Patients With No Therapeutic Alternative	
Principal Investigator: CPT Scott C. Martin, MS (formerly: LTC William C. Browning, MS)	
Associate Investigators: COL Jeffrey L. Berenberg, MC; MAJ Bruce A. Cook, MC; LTC William J. Uphouse, MC; MAJ Luke Stapleton, MC	
Department/Section: Pharmacy Service/Oncology	
Key Words: hyperuricemia; allopurinol	
Funding: FY 87: NA	FY 88: \$800.
Gifts: Allopurinol	Periodic Review Date: Sep 88 Decision: Continue

OBJECTIVE: To provide a water soluble form of allopurinol that can be given intravenously to patients with hyperuricemia who are too ill to take oral medication.

TECHNICAL APPROACH: This is a "convenience" protocol to make an uncommonly required dosage form available for use without the need for individual, special exception approval of the committee for each patient. This study also centralizes and simplifies the procedures for requesting the drug for patients. It is anticipated that 1-2 patients a year will be treated on this protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 9 Reporting Period: 1

One patient enrolled in FY88. Protocol to continue as a "convenience protocol" for use on an as needed basis. Status is ongoing.

Detail Summary Sheet

Prot No: NSABP B13(84)	Status: Ongoing
TITLE: A Protocol to Assess Sequential Methotrexate-5-FU in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Negative for Estrogen Receptor	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: Fluorouracil and Leucovorin	Decision: Continue

OBJECTIVE: To determine if giving a relatively nontoxic chemotherapy program to women after surgery will decrease the chances of relapse and improve survival.

TECHNICAL APPROACH: All eligible patients are randomized to receive (1) chemotherapy with 5-FU and methotrexate twice a month for 1 year or (2) no treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 6 Reporting Period: 2

The patients entered have tolerated the chemotherapy very well. National results shows improved disease-free survival (which was significant) in that treated vs. the untreated group. So far there has been no improvement in overall survival. The protocol was just amended so that all new patients are placed on the therapy arm. This protocol will be closing soon.

Detail Summary Sheet

Prot No: NSABP B14(84)	Status: Ongoing
TITLE: A Protocol to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Positive for Estrogen Receptors	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: Tamoxifen	Decision: Continue

OBJECTIVE: To determine if Tamoxifen given to women after surgery for breast cancer will prolong survival and prevent recurrences.

TECHNICAL APPROACH: All patients who are eligible are randomized to tamoxifen p.o. for 4 years or placebo p.o. for 4 years.

PROGRESS: No. of Subjects Enrolled - To Date: 11 Reporting Period: 3

Nationally the tamoxifen arm of the study have just demonstrated a significantly improved disease-free survival over the placebo arm. So far there has been no difference in overall survival between the 2 arms. Because of this, all patients entering the study from now on will be on the tamoxifen arm. This study will be closing soon.

Detail Summary Sheet

Prot No: NSABP B15(84)	Status: Ongoing
TITLE: A Three-Arm Clinical Trial Comparing Short Intensive Chemotherapy With or Without Reinduction Chemotherapy to Conventional CMF in Receptor-Negative Positive-Node Breast Cancer Patients	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine if a short course of chemotherapy in the adjuvant setting is as effective as the "standard" six months of CMF. Also, to determine if a later "reinduction" will improve survival.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to one of three treatment groups: (1) Adriamycin and Cytosan for four cycles, (2) Adriamycin and Cytosan as above, then, after six months of rest, three cycles of CMF, or (3) six cycles of CMF ("standard" therapy).

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 1

Patients entered to date at TAMC are doing well. No national data available yet.

Detail Summary Sheet

Prot No: NSABP B16(84)	Status: Ongoing
TITLE: A Three-Arm Clinical Trial Comparing Tamoxifen Alone Versus L-PAM, 5-FU, and Tamoxifen Versus Short Intensive Adriamycin-Cyclophosphamide Plus Tamoxifen in Receptor-Positive Node-Positive Breast Cancer Patients	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jan 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine if chemotherapy added to tamoxifen is superior to tamoxifen alone in the adjuvant therapy of receptor-positive breast cancer. Also, to determine which of two chemotherapy regimens, when added to tamoxifen, results in the best survival.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to one of three treatments: (1) tamoxifen alone for four years, (2) tamoxifen for four years, plus four cycles of Adriamycin and Cytosan, or (3) tamoxifen for four years, plus L-PAM and 5-FU every six weeks for 17 courses.

PROGRESS: No. of Subjects Enrolled - To Date: 4 Reporting Period: 1

Four Tripler patients have been entered to date. It is too early for any analyses. No national data are available.

Detail Summary Sheet

Prot No: NSABP B17(86)	Status: Ongoing
TITLE: A Clinical Trial to Evaluate Natural History and Treatment of Patients with Noninvasive Intraductal Adenocarcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas; LTC Aida P. Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: adenocarcinoma, noninvasive intraductal	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88 Decision: Continue

OBJECTIVE: To determine whether lumpectomy is an effective operation for the treatment of noninvasive breast cancer and if radiation treatments add to that effectiveness.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized after lumpectomy to receive or not receive radiation therapy to the involved breast.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This protocol is still relatively new. We do expect to accrue patients per Dr. Lee in General Surgery Service, Department of Surgery.

Detail Summary Sheet

Prot No: NSABP C02(84)

Status: Terminated

TITLE: A Clinical Trial Evaluating the Postoperative Portal Vein Infusion of 5-FU and Heparin in Patients with Resectable Adenocarcinoma of the Colon

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: LTC William Uphouse MC; COL Peter J. Barcia, MC;
LTC Margaret Lee, MC

Department/Section: Medicine/Hematology-Oncology

Key Words: colon adenocarcinoma

Funding: FY 87: NA FY 88: \$800.

Periodic Review Date: Aug 88

Gifts: None

Decision: Terminate

OBJECTIVE: To determine if 5-FU infused through the portal vein for one week postoperatively will decrease the recurrence rate of operable adenocarcinoma of the colon in comparison to a control group given no therapy.

TECHNICAL APPROACH: Patients who appear to have Dukes A, B, or C colon cancer and who agree to participate will be randomized preoperatively to receive a 5-FU and heparin infusion via the portal vein for 7 days postoperatively or to receive no further therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 7

Reporting Period: 5

Seven Tripler patients have been entered to date. Nationally, several hundred patients were randomized. Preliminary toxicity analysis indicates no bone marrow or surgical toxicity. This study has just been terminated as it has reached its target number of patients. No results have been released.

Detail Summary Sheet

Prot No: POG 8104(83)	Status: Ongoing
TITLE: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: neuroblastoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Aug 88
Gifts: VM-26	Decision: Continue

OBJECTIVE: Attempts to reduce later complications by separating by age and stage those patients that require surgery only, surgery and chemotherapy, surgery, chemotherapy, and radiation therapy, etc.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under the age of 18 with neuroblastoma are eligible for enrollment in this study. Treatment will be as outlined in the study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 5 Reporting Period: 0

With the opening of new POG protocols, this study has now been limited to:

- 1) Newly diagnosed Stage A.
- 2) Newly diagnosed Stage C. (Age >365 days).
- 3) Newly diagnosed Stage Ds (Surgery only option).
- *4) Stage A Recurrence (if >365 days).
- *5) Stage A Recurrence (if <365 days, Stage C or D at recurrence).
- *6) Stage B, C, D failure.

*All recurrences must have been previously registered on POG 8104.

Detail Summary Sheet

Prot No: POG 8158(83)	Status: Ongoing
TITLE: NWTS Long Term Follow-up Study	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Wilm's tumor	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88
	Decision: Continue

OBJECTIVE: To examine the late consequences of successful treatment given for Wilms' tumor.

TECHNICAL APPROACH: Pediatric patients and adolescent patients under 18 years of age with Wilms' tumor will be eligible. Treatment will be as outlined in the study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been entered into this protocol as yet. This is a non therapeutic study designed to gather epidemiologic and late effects data on long term (>5yrs) survivors of Wilm's tumor. No Tripler patients have been registered to date. Nationally 154 patient registrants have been accrued. No detailed results are available yet and the study remains open.

Detail Summary Sheet

Prot No: POG 8346(85)	Status: Ongoing
TITLE: Comprehensive Therapy for Ewing's Sarcoma: Tailored Versus Standard Radiation Therapy, Phase III	
Principal Investigator: LTC Bruce A. Cook, MC;	
Associate Investigators: LTC Joseph Woods, MC; COL Peter Barcia, MC	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Ewing's sarcoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Aug 88
Gifts: None	Decision: Continue

OBJECTIVE: This study is directed toward comprehensive care of the child with Ewing's Sarcoma. Several questions are being asked in this study, but there are essentially two major points to the investigation: (1) Do sequential cyclophosphamide and Adriamycin produce complete or partial responses as well as group and historical controls? (2) Is local tumor control achieved as well with radiation therapy to a small field (tumor plus margin) as compared to the standard whole bone field?

TECHNICAL APPROACH: After initial induction chemotherapy, patients are evaluated to assess completeness of response. Patients are then randomized to small field or whole bone radiation.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

One TAMC patient have been registered on this protocol, it remains open to patient entry. One abstract has been accepted utilizing data from this study - SIOP - 1985. At 48 months follow-up survival in all patients is 60%.

Detail Summary Sheet

Prot No: POG 8361(84)	Status: Terminated
TITLE: VP 16-213 and 5-Azacytidine in Combination For Refractory Acute Nonlymphocytic Leukemia (ANLL), Phase II	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: leukemia, nonlymphocytic	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Aug 88
Gifts: VP-16	Decision: Terminate

OBJECTIVE: Patients with ANLL under 21 years of age with disease refractory to standard drugs will be given a combination of nonstandard drugs shown to be effective in pilot studies. The objective is to improve response in these patients.

TECHNICAL APPROACH: This phase II study will test whether increasing the dose of VP-16 will produce hypoplasia in two versus three courses and improve response.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been registered. The study is now closed. An abstract was published. AACR May 1985, pp. 22-25. A total of 155 patients were entered on the study nationally, 15 patients survived greater than 1 year; 5 remain alive and disease free.

Detail Summary Sheet

Prot No: POG 8426(86)	Status: Terminated
TITLE: Intensive Chemotherapy (MOPP-ABVD) Plus Low-Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, III ₂ A, IIIB, IV Hodgkin's Disease in Pediatric Patients, A Groupwide Pilot Study	
Principal Investigator: LTC Bruce A. Cook, MC; Associate Investigators: LTC Joseph Woods, MC;	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Hodgkin's disease	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Feb 88
Gifts: None	Decision: Terminate

OBJECTIVE: To determine if the addition of total nodal radiation therapy to standard chemotherapy will aid in disease-free survival and overall care.

TECHNICAL APPROACH: In this study, patients will receive alternating courses of MOPP-ABVD chemotherapy, with each course lasting 28 days. A cycle of therapy will consist of one course of MOPP and ABVD--thus a cycle equals 56 days. After 1½ cycles (3 months), clinical restaging will be performed (CT scans, chest x-ray, and possible biopsy). If the disease has not worsened, 1½ additional cycles will be given; then a second restaging will occur. Once again, as long as the disease has not worsened, the patient will receive an additional cycle of MOPP-ABVD. After a 6-week rest, a complete clinical restaging will be done, possibly including biopsy. If the patient is in complete remission, low-dose total nodal irradiation will be given. If, however, disease is present, no irradiation will be given and the patient will be off the study.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

67 patients have been registered nationally and this is an adequate number to answer the study question. At this time, 62 patients have sufficient data for analysis and 54 (87%) remain disease free at follow-up of 4-37 months.

Detail Summary Sheet

Prot No: POG 8451(86)	Status: Ongoing
TITLE: Intergroup Rhabdomyosarcoma - Study III	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatric/Hematology-Oncology	
Key Words: rhabdomyosarcoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Oct 88
Gifts: Drugs	Decision: Continue

OBJECTIVE: This protocol is the new Intergroup Rhabdomyosarcoma III study designed to provide definitive care to all new cases of rhabdomyosarcoma less than 21 years of age.

TECHNICAL APPROACH: Multiagent chemotherapy and radiotherapy tailored to: site of disease, histologic subtype and stage of disease. Results will be compared to IRS I & II (historical controls).

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

One Tripler patient has been enrolled in this study. The patient is 20 months into therapy and has done very well with minimal toxicity. Nationally 256 patients have been entered in the study. No abstracts or publications have been published at this time.

Detail Summary Sheet

Prot No: POG 8461(85)	Status: Terminated
TITLE: Protocol for Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia, a Group-Wide Pilot Study	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: LTC Joseph Woods, MC	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Leukemia, acute lymphocytic	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Aug 88
Gifts: VM-26; Leucovorin	Decision: Terminate

OBJECTIVE: This study will employ VM-26 with continuous infusion ARA-C in an attempt to induce marrow remission in children with ALL who fail initial chemotherapy induction. This protocol will also look at drug resistance as correlated with the presence or absence of cell surface resistance associated protein and gene amplification of dihydrofolate reductase.

TECHNICAL APPROACH: Nonrandomized study of intensive therapy in a high-risk group of ALL patients. Included is a biologic evaluation of the clinically resistant tumor cells to determine if induction failures can be predicted or prevented in future front-line studies.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been entered on this protocol.

Abstract: Ocks J, Rivera GK, Buchanan G, Freeman AI. VM-26 and continuous infusion cytosine arabinoside (ARA-C) for initial induction failure patients with childhood ALL. ASCO, 1988.

Detail Summary Sheet

Prot No: POG 8493(85)	Status: Ongoing
TITLE: Infant Leukemia Protocol, Group-Wide Pilot	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: LTC Joseph C. Woods, MC	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Infant Leukemia	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Sep 88
Gifts: VM-26	Decision: Continue

OBJECTIVE: To study biologic differences of acute lymphocytic leukemia (ALL) in infants and improve the very poor disease-free survival in this group. A major objective is to identify toxicities and determine criteria for dose modification in infants.

TECHNICAL APPROACH: All patients will be treated with the same regimen and response rates will be compared to 75 controls from POG's previous ALL studies.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been enrolled in this study, which remains open at this time.

Abstracts: Blood 6S(S): 252A, 1986.
Proc. ASCO Vol. 6:161, 1987.

Detail Summary Sheet

Prot No: POG 8498(87) Status: Terminated

TITLE: Treatment of Children with Newly Diagnosed Acute Non-Lymphocytic Leukemia (ANLL) Using High-Dose Cytosine Arabinoside and Etoposide Plus 5-Azacytidine for Intensification of Early Therapy

Principal Investigator: LTC Bruce A. Cook, MC
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology

Key Words: Acute Non-Lymphocytic Leukemia (ANLL); 5-Azacytidine

Funding: FY 87: NA FY 88: \$800. Periodic Review Date: Apr 88
Gifts: VP-16; 5-Azacytidine; Ara-C; Decision: Terminate
Cytosan; 6-Thioguanine;
Daunomycin

OBJECTIVE: (a) To explore the efficacy and feasibility of utilizing sequential courses of high-dose cytosine arabinoside (Hd A) and etoposide (VP) plus 5 azacytidine (AZ) for intensification of early therapy immediately following standard remission induction with daunomycin, Ara-C, and 6-thioguanine (DAT) in children with ANLL. (b) To determine the immediate and delayed toxicity of the above intensification method.

TECHNICAL APPROACH: The addition of an early intensification using sequential courses of drugs shown to be effective in resistant ANLL to the current most effective treatment regimen for childhood ANLL.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 1

Two TAMC patients have been registered to date. 193 patients have been registered nationally - 157/193 are fully evaluable. Continuous remission rate is about 35% at 2 years. All patients have experienced grade IV hemotopoietic toxicity as expected. Two cases of acute cerebellar toxicity have occurred, one patient resolved completely and the other died of infections complications. Overall incidence of sepsis has been about 13%.

Abstract ASCO, 1987.

Detail Summary Sheet

Prot No: POG 8552(85)	Status: Ongoing
TITLE: A Case Control Study of Childhood Rhabdomyosarcoma	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: rhabdomyosarcoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Sep 88
Gifts: None	Decision: Continue

OBJECTIVE: To evaluate the relationships between environmental exposures, gestational factors, and genetic factors in childhood rhabdomyosarcoma.

TECHNICAL APPROACH: Data will be collected by telephone interview conducted by the Intergroup Rhabdomyosarcoma Group and by a questionnaire. These data will be correlated with biologic data collected from treatment protocol forms.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been enrolled on this study to date. It remains open.

56 patients registered nationally.

Publication: J Clin Oncology 2:670-675, 1984.
Med Hypotheses 12:17-20, 1983.

Detail Summary Sheet

Prot No: POG 8561(87)	Status: Ongoing
TITLE: Phase II Study of 6-Mercaptopurine Administered as an Intravenous Infusion for Malignant Solid tumors and Acute Leukemia	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology/Oncology Service	
Key Words: acute leukemia; 6-Mercaptopurine	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Sep 88
	Decision: Continue

OBJECTIVE: a. To determine response rate of children with advanced malignant disease for whom no effective anti-cancer therapy is known to treatment with 6-mercaptopurine (6-MP) administered as a 48-hour IV infusion.
b. to further assess the toxicity in a larger group of children.

TECHNICAL APPROACH: a. Patients will be given 6-MP, $1.2 \text{ gm/M}^2/\text{day} \times 48$ hours by continuous infusion. Dilution = 1 mg/ml as a 48-hr infusion at the dose rate of $50 \text{ mg/M}^2/\text{hr}$. b. Treatment frequency: Cycles will be repeated every 21 days if counts are adequate: ANC must be $\geq 1500 \text{ } \mu\text{l}$ and platelets $> 100,000/\text{ } \mu\text{l}$ unless BM compromised.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Nationally 108 patients have been entered in this study. Toxicity has been as expected, pancytopenia, alopecia, stomatitis and nausea/vomiting. Some hepatic and renal toxicity of grade 2-3 have been reported but the majority have not experienced toxicity in this area.

Detail Summary Sheet

Prot No: POG 8600/01/02 (86)	Status: Ongoing
TITLE: Laboratory Classification in Acute Lymphoid Leukemia of Childhood (ALinC 14C), Phase III	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Leukemia	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Feb 88
Gifts: None	Decision: Continue

OBJECTIVE: To thoroughly classify by laboratory methods the type of leukemia in children newly diagnosed with ALL, to see if better characterization of newly diagnosed leukemia can better define different prognostic groups. To provide comprehensive care of children newly diagnosed with ALL.

TECHNICAL APPROACH: Multiagent chemotherapy of ALL. Results of therapy will be compared to previous POG protocols for therapy of ALL which serve as historical controls. Data will be used to construct new treatment regimens based on prognostic groups and previous therapeutic studies.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 2

Three Pediatric patients enrolled at this time. 886 patients have been entered into this study nationally. It appears that chromosome Ploid, is an important prognostic factor. Event free survival for all patients at 18 months follow-up is about 80%.

Publication: Blood 70(6): 1962-1965, 1987.

Detail Summary Sheet

Prot No: POG 8617/18(87)	Status: Ongoing
TITLE: Therapy for B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology Oncology Service	
Key Words: acute lymphocytic leukemia;	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Sep 88
Gifts: None	Decision: Continue

OBJECTIVE: a. To estimate the complete remission (CR) rate in patients with Stage IV diffuse undifferentiated non-Hodgkin's lymphoma (DU NHL) and B-cell acute lymphocytic leukemia (B-ALL) with a new schedule of administration of three active agents: "split-dose" cyclophosphamide (cyclo) + Adriamycin (Adria) + vincristine (VCR). b. To estimate chemotherapeutic cure rate in Stage IV DU NHL and B-ALL with a brief (6 months) intensive rotational chemotherapy program designed to confer greater protection against central nervous system (CNS) disease and marrow relapse. c. To estimate the reinduction rate and disease-free survival rate for patients in relapse with non-lymphoblastic lymphoma.

TECHNICAL APPROACH: All patients are treated with four cycles of high dose cytoxan, vincristine, daunomycin plus IT therapy with MTX and ARA-C alternated with 4 cycles of high dose MTX, high dose ARA-C and IT MTX and ARA-C.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

New start.

Detail Summary Sheet

Prot No: POG 8631 (87)	Status: Ongoing
TITLE: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs. Standard Dose Irradiation	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology/Oncology	
Key Words: medulloblastoma; radiation	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Feb 88
Gifts: None	Decision: Continue

OBJECTIVE: To see if reduced irradiation to the spinal contents and supratentorial area of the brain can achieve an equal rate of disease-free survival and a lesser degree of psychomotor retardation as compared to standard dose irradiation.

TECHNICAL APPROACH: All registered children will be randomized into one of two treatment arms (a) Arm 1--3600 rads to whole brain and spinal contents plus an additional 1800 rads to posterior fossa, and (b) Arm 2--2340 rads to whole brain and spinal contents plus an additional 3060 rads to posterior fossa.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No Tripler patients have been enrolled in this study. 20 patients have been entered nationally on this study.

Detail Summary Sheet

Prot No: POG 8651(86)	Status: Ongoing
TITLE: Osteosarcoma Study #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Nonmetastatic Osteosarcoma, Phase III	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatric/Hematology-Oncology	
Key Words: osteosarcoma, chemotherapy	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Dec 88
Gifts: Methotrexate	Decision: Continue

OBJECTIVE: To compare delayed surgery group to their immediate surgery controls to see if (1) those patients considered ineligible for limb salvage can be converted to candidates for limb salvage, and (2) preoperative chemotherapy improves disease-free survival.

TECHNICAL APPROACH: Multiagent chemotherapy utilizing methotrexate, adriamycin, cis-platinum, Bleomycin, Actinomycin-D and Cytosan over 42 weeks. One half of patients are randomized to immediate therapy. The remainder receive 10 weeks of adjuvant chemotherapy prior to definitive surgery.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 3

3 TAMC patients have been enrolled in this study. Toxicity has been primarily hematopoietic. Bleomycin induced (transient) pulmonary toxicity was noted in one patient. Two patients are alive and well with no evidence of active disease. One TAMC patient has died of recurrent disease. Twenty-two patients have been registered nationally.

Detail Summary Sheet

Prot No: POG 8696/97(87)	Status: Ongoing
TITLE: Treatment of Hepatoblastoma (HB) with Surgery, Chemotherapy, and Radiation Therapy	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Hepatoblastoma (HB)	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Apr 88 Decision: Continue

OBJECTIVE: This is a study directed toward comprehensive care of the child with hepatoblastoma. There is only scattered data on therapy or survival in this relatively rare tumor of childhood. This study will involve single arm studies of each stage of the disease using the anticipated best available therapy for each stage. This study will establish a benchmark for future therapies and explore the importance of several factors including: 1) Histology 2) Modern studying and surgical therapy, 3) Alpha-fetoprotein levels, 4) chemotherapy (cis-platinum, vincristine, 5-FU for 80 days), and 5) Radiotherapy to localized unresectable disease.

TECHNICAL APPROACH: These are single armed studies stratified by stage. There is no randomization.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Nationally 28 fully evaluable patients are available. No Stage I or II with resected disease has recurred. All patients with measurable disease have had at least a partial response to chemotherapy.

Detail Summary Sheet

Prot No: POG 8725(88)	Status: Ongoing
TITLE: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) + Low-Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, ITIA ₂ , IIIB, IV Hodgkin's Disease in Pediatric Patients	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/ Pediatric Hematology/Oncology Section	
Key Words: total nodal radiation therapy (TNRT);	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Sep 88 Decision: Continue

OBJECTIVE: a. To determine, in a randomized study, whether the addition of Low-dose total nodal radiation therapy (TNRT) in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of ABVD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone. b. To determine whether TNRT will significantly (i.e., grade 3 or 4) increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone. c. To determine the effect of chemotherapy as compared to chemotherapy plus TNRT on splenic function as determined by the pitted erythrocyte count using Nomarski optics.

TECHNICAL APPROACH: Randomized treatment study (National protocol).

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

New start.

Detail Summary Sheet

Prot No: POG 8741/42(87)	Status: Ongoing
TITLE: Treatment of Stage D Neuroblastoma in Children Greater Than or Greater to 365 Days at Diagnosis	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: neuroblastoma;	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jul 88
Gifts: None	Decision: Continue

OBJECTIVE: This study is designed to look specifically at children in the worst prognostic groups of neuroblastoma. This study will employ four phase two agents in addition to standard chemotherapy.

TECHNICAL APPROACH: Children will be randomized to receive one of 4 phase two agents as initial drug therapy. After two courses they will then be randomized to one of two standard treatment arms for completion of therapy. Results will be compared to historical group controls.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No patients registered/treated on this study to date from TAMC. Nationally 69 patients have been registered. 18 patients have experienced severe granulocytopenia and/or lymphopenia from Ifosfamide. Two cases of uremia and one case of severe somnolence have occurred.

Detail Summary Sheet

Prot No: POG 8764(88)	Status: Ongoing
TITLE: Chemotherapy Regimen for Early and Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase II Study	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology/Oncology Section	
Key Words: Lymphoblastic leukemia	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: May 88 Decision: Continue

OBJECTIVE: To estimate the complete remission rate for early and initial induction failures in childhood ALL based on an induction regimen of VM-26 and continuous infusion cytosine arabinoside (Ara-C); to estimate the one-year disease-free survival for early and initial induction failures in childhood ALL, based on a new regimen; to try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

TECHNICAL APPROACH: Remission induction with standard dose continuous ARA-C, high dose VM-26 and TIT. Continuation therapy with MTX, ARA-C, VM-26, Daunomycin and 6-MP.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

No other data available.

Detail Summary Sheet

Prot No: POG 8821(88)	Status: Ongoing
TITLE: AML#3: Intensive Multiagent Therapy vs. Autologous Bone Marrow Transplant Early in First CR for Children with Acute Myelocytic Leukemia	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics	
Key Words: acute myelocytic leukemia;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: a) To determine the disease-free survival (DFS) and event-free survival (EFS) in childhood acute myelocytic Leukemia (AML) offered by intensive chemotherapy with alternating non-cross resistant drug combinations for nine courses. b) To determine if short (three course) intensive chemotherapy (identical to the first three courses of the above regimen) followed by autologous bone marrow transplant (BMT) using the Busulfan/Cytosan preparative regimen and 4-Hydroperoxycyclophosphamide (4-HC) purged marrow is effective therapy. c) To compare, in a randomized study, the results of the above two regimens. d) To correlate the treatment outcome with clinical and laboratory features.

TECHNICAL APPROACH: Patients to be equally randomized (after remission induction with 6-TG, ARA-C and Daunomycin to standard chemotherapy for maintenance or autologous bone marrow with 4-HC purging and no further therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

New start.

Detail Summary Sheet

Prot No: SWOG 7804(84)	Status: Ongoing
TITLE: Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin C (FAM) versus Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; COL Peter J. Barcia, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: gastric adenocarcinoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jul 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine whether or not chemotherapy (FAM) given to patients with advanced but resected gastric carcinoma will prevent relapses and prolong life.

TECHNICAL APPROACH: Patients will be randomized to either (1) receive chemotherapy with FAM twice a month for 1 year for (2) receive no treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

National accrual continues and completion of this study will hopefully be in the near future.

Detail Summary Sheet

Prot No: SWOG 7808(83)	Status: Terminated
TITLE: Combined Modality Treatment for Stage III and IV Hodgkin's Disease - MOPP 6, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; MAJ Marianne Young, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Hodgkin's disease	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: None	Decision: Terminate

OBJECTIVE: To determine if radiation therapy given after the chemotherapy will increase the chance of being cured, and to see if a drug called levamisole given as a pill will increase the chance of being cured.

TECHNICAL APPROACH: As outlined in study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 13 Reporting Period: 13

This study has been terminated as it has reached its target number of patients. So far there is no difference in overall survival between the chemotherapy alone arm and the chemotherapy plus radiation arm.

Detail Summary Sheet

Prot No: SWOG 8107(84)	Status: Terminated
TITLE: Management of Disseminated Melanoma Master Protocol	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: melanoma, disseminated	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Jul 88
Gifts: None	Decision: Terminate

OBJECTIVE: To determine the relative activity of three chemotherapy programs in patients with metastatic melanoma: (1) DTIC and Actinomycin-D (2) Cis-platinum, and (3) Cis-platinum, Velban, and Bleomycin. In addition, to determine if prophylactic cranial irradiation will prevent the later development of brain metastases.

TECHNICAL APPROACH: Patients with metastatic melanoma are randomized to receive or not to receive 5 days of prophylactic cranial radiation. They are also randomized to receive one of the three chemotherapy programs listed above.

PROGRESS: No. of Subjects Enrolled - To Date: 6 Reporting Period: 0

This protocol has accrued its targeted number of patients and is no longer open to patient accrual. The results of the different arms of treatment have not yet been released.

Detail Summary Sheet

Prot No: SWOG 8300(84)	Status: Terminated
TITLE: Treatment of Limited Non-small Cell Lung Cancer: Radiation Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: lung cancer, non-small cell	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: None	Decision: Terminate

OBJECTIVE: To determine whether chemotherapy added on to standard radiation therapy in patients with limited, non-small cell lung cancer will improve response rates and survival.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive (1) definitive radiation therapy alone, or (2) 8 weeks of FOMi/CAP followed by definitive radiation and then two further cycles of FOMi/CAP. All patients are also randomized to receive or not receive prophylactic cranial irradiation.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

Two Tripler patient were registered on this protocol. Accrual has been good and no unusual or unanticipated toxicity has occurred. This study has been terminated recently as it has accrued its target number of patients. No data on the results have been released yet.

Detail Summary Sheet

Prot No: SWOG 8312(85)

Status: Ongoing

TITLE: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Metastatic Breast Cancer, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: MAJ William Uphouse, MC; LTC Joseph Woods, MC

Department/Section: Medicine/Hematology-Oncology

Key Words: breast cancer, metastatic

Funding: FY 87: NA FY 88: \$800.

Periodic Review Date: Jan 88

Gifts: None

Decision: Continue

OBJECTIVE: To determine if combined hormone therapies are superior to single hormone therapy in sequence for metastatic breast cancer.

TECHNICAL APPROACH: All patients agreeing to this study will be randomized to one of three treatments: (1) megestrol acetate, (2) aminoglutethimide plus hydrocortisone, or (3) megestrol acetate plus aminoglutethimide plus hydrocortisone.

PROGRESS: No. of Subjects Enrolled - To Date: 0

Reporting Period: 0

There are no TAMC patients on this study. Study remains open with no unanticipated toxicity. Accrual is adequate.

Detail Summary Sheet

Prot No: SWOG 8324(87)	Status: Ongoing
TITLE: Evaluation of Fludarabine Phosphate in Malignant Melanoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: fludarabine phosphate; metastatic melanoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine the response rate and response duration in patients with malignant melanoma treated with fludarabine phosphate.

TECHNICAL APPROACH: Patients agreeing to participate will receive fludarabine IV push daily for 5 days every 4 weeks until relapse.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No data yet. Protocol still open.

Detail Summary Sheet

Prot No: SWOG 8326/27(85)	Status: Ongoing
TITLE: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blast Crisis, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke M. Stapleton, MC; MAJ Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: leukemia, adult acute; leukemia, chronic granulocytic	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To determine the response and response duration of a high-dose program of Ara-C in patients with relapsed acute leukemia.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive (1) six days of high dose Ara-C, (2) the same Ara-C plus three days of m-AMSA, or (3) the same Ara-C plus three days of Mitoxantrone.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

Accrual has been slow nationally to date but continues. High dose Ara-C continues to be the most promising drug in relapsed leukemia. The one TAMC patient registered on this study has already achieved a complete remission of her leukemia.

Detail Summary Sheet

Prot No: SWOG 8390(84)	Status: Terminated
TITLE: Chemotherapy of Gastric Cancer with 5-FU and Folinic Acid, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: gastric cancer	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Aug 88
Gifts: Folinic acid	Decision: Terminate

OBJECTIVE: To determine the response rate of metastatic gastric carcinoma to a new combination of drugs (5-FU and folinic acid).

TECHNICAL APPROACH: Patients who agree to participate will be randomized to receive 5-FU either by constant IV infusion on day 1 through day 4, or by IV bolus on day 1 through day 5. Folinic acid will be given in both arms by IV bolus on each day of 5-FU. Courses will be repeated monthly.

PROGRESS: No. of Subjects Enrolled - To Date: 5 Reporting Period: 2

There are five TAMC patients on this study. Toxicity has been acceptable. Preliminary results per Dr. Berenberg are that this program is achieving results similar to 5-FU. Final results are pending.

Detail Summary Sheet

Prot No: SWOG 8393(84)	Status: Ongoing
TITLE: National Intergroup Protocol for Intermediate Thickness Melanoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; COL Peter J. Barcia, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: melanoma	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88
	Decision: Continue

OBJECTIVE: (1) To determine the optimal surgical margins (2 versus 4 cm) around the intermediate thickness melanomas (1-4 mm) that are being resected for cure. (2) To evaluate the value of elective regional lymph node dissection in these same melanomas.

TECHNICAL APPROACH: Patients with primary melanomas of the head or neck or distal extremities will be randomized to receive or not receive elective node dissection, but all patients in this group will have 2 cm surgical margins. Patients with melanomas of the trunk or proximal extremities will undergo two randomizations, (1) to receive or not to receive elective node dissection, and (2) to have either a 2 or 4 cm surgical margin.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 1

Two Tripler patients have been registered on this protocol. It is too early to assess efficacy of this protocol approach.

Detail Summary Sheet

Prot No: SWOG 8406(87)	Status: Terminated
TITLE: Evaluation of Esorubicin in Malignant Lymphoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: esorubicin; malignant lymphoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: None	Decision: Terminate

OBJECTIVE: To determine the response rate and response duration of malignant lymphoma treated with esorubicin.

TECHNICAL APPROACH: Patients agreeing to the study will receive esorubicin IV over five minutes every three weeks until progression of their tumor.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 1

Two TAMC patients entered to date. Nationally esorubicin (the drug) has been showing activity, but final report is pending. This study has been terminated as it has accrued its target number of patients.

Detail Summary Sheet

Prot No: SWOG 8417/19(85)	Status: Ongoing
TITLE: Evaluation of the Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Leukemia, Lymphoblastic	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Sep 88
Gifts: None	Decision: Continue

OBJECTIVE: To compare two consolidation chemotherapy programs in terms of remission, duration, and survival.

TECHNICAL APPROACH: All patients agreeing to participate will be randomized to receive either the L-10M consolidation or the new (shorter) consolidation program.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

One TAMC patient has been entered into this study to date. This study is the frontline study for patients with newly diagnosed acute lymphoblastic lymphoma and remains open.

Detail Summary Sheet

Prot No: SWOG 8505(86)	Status: Terminated
TITLE: Evaluation of Echinomycin in Advanced Soft Tissue Sarcomas, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke M. Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: sarcoma, soft tissue	
Funding: FY 87: NA	FY 88: \$800.
Gifts: Echinomycin	Periodic Review Date: Sep 88 Decision: Terminate

OBJECTIVE: To assess anti-tumor activity in patients with advanced sarcomas when treated with Echinomycin.

TECHNICAL APPROACH: Patients agreeing to participate will receive Echinomycin once a week IV for four weeks, then rest two weeks, then repeat the sequence.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This protocol was approved in September 1986. This study has been terminated as it has accrued its target number of patients nationally. No activity (as defined by greater than 50% tumor shrinkage) was seen.

Detail Summary Sheet

Prot No: SWOG 8507(86)	Status: Ongoing
TITLE: Maintenance vs No Maintenance BCG Immunotherapy of Superficial Bladder Cancer, Phase III	
Principal Investigator: COL Martin L. Dresner, MC (formerly: COL Douglas Soderdahl, MC)	
Associate Investigators: LTC W. Kennon, MC; MAJ F. Sateri, MC; CPT Karl Kreder, MC; CPT M. Pliskin, MC; LTC Lawrence Sakas, MC	
Department/Section: Surgery/Urology Svc	
Key Words: bladder cancer	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: BCG NSC B116341	Decision: Continue

OBJECTIVE: To compare effectiveness of maintenance vs no maintenance BCG and to assess relative toxicities of these two approaches and to assess the association of intermediate strength PPD skin test reactivity with disease-free status in patients so treated.

TECHNICAL APPROACH: Patients who meet criteria and who consent to participate will be registered for induction treatment, then randomized at a second registration. BCG Connaughtis is diluted in 50.5 cc sterile saline and 50 cc is placed intravesically for two hours, 0.5 cc is administered subcutaneously to the upper thigh. Maintenance patients receive similar therapy weekly every six weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 7 Reporting Period: 2

Study completed by departed investigator. Data being collected at SWOG.

Detail Summary Sheet

Prot No: SWOG 8509(86)	Status: Ongoing
TITLE: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: prostate adenocarcinoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Mar 88
Gifts: Menogaril	Decision: Continue

OBJECTIVE: To determine the response rate of metastatic prostate cancer to a new Adriamycin-like drug, Menogaril, in patients who have failed hormone therapy.

TECHNICAL APPROACH: Patients agreeing to the study will receive the drug once every 28 days IV over one hour.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

One TAMC patient entered to date.

Detail Summary Sheet

Prot No: SWOG 8514(86)	Status: Ongoing
TITLE: Randomized Comparison of Cisplatin + 5-Fluorouracil vs. CBDCA + 5-Fluorouracil vs. Methotrexate in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: carcinoma, squamous cell	
Funding: FY 87: NA	FY 88: \$800.
Gifts: CBDCA	Periodic Review Date: Mar 88
	Decision: Continue

OBJECTIVE: To compare the response rate of two relatively new chemotherapy combinations (5-FU + Cisplatin vs. CBDCA + 5-FU) with standard therapy, i.e., methotrexate, in advanced head and neck cancer.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive one of three regimens: (1) methotrexate IV weekly, (2) Cisplatin + 5-FU IV every 4 weeks, or (3) CBDCA + 5-FU IV every 4 weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

Two patients entered to date for TAMC. At least one of the two has done very well on the carboplatin arm.

Detail Summary Sheet

Prot No: SWOG 8516(86)	Status: Ongoing
TITLE: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBOM vs MACOP-B in Patients with Intermediate and High-Grade Non-Hodgkin's Lymphoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: Lymphoma, non-Hodgkin's	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88
	Decision: Continue

OBJECTIVE: To determine which of the four leading chemotherapy programs for aggressive lymphomas is best in terms of response, survival, and toxicity.

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive one of the four treatment programs listed above.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

We have been slow to accrue non-Hodgkin's cases because these cases have been relatively uncommon hospital-wide this year. The one patient entered at TAMC has gone into a complete remission.

Detail Summary Sheet

Prot No: SWOG 8530(86)	Status: Ongoing
TITLE: Efficacy of Prednisone in Refractory and Relapsing Multiple Myeloma and Measurement of Glucocorticoid Receptors, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC, MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: myeloma; glucocorticoid receptors	
Funding: FY 87: NA	FY 88: \$800.
Gifts: none	Periodic Review Date: Sep 88 Decision: Continue

OBJECTIVE: To estimate the response rate and duration of response with high dose prednisone in patients with refractory myeloma.

TECHNICAL APPROACH: Patients agreeing to participate will receive 100 mg of prednisone every other day for two weeks, then 50 mg every other day for ten weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

This protocol was approved in September 1986. The one patient entered at Tripler has had an excellent response to this therapy.

Detail Summary Sheet

Prot No: SWOG 8561(86)	Status: Terminated
TITLE: V-TAD for Patients Greater than 50 Years of Age with Acute Non-lymphocytic leukemia.	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology/Oncology	
Key Words: leukemia, non-lymphocytic	
Funding: FY 87: NA	FY 88: \$800.
Gifts: none	Periodic Review Date: Sep 88 Decision: Terminate

OBJECTIVE: To determine the complete remission rate and toxicity of a new chemotherapy regimen in individuals greater than 50 years of age with acute non-lymphocytic leukemia.

TECHNICAL APPROACH: Patients agreeing to participate will receive "V-TAD" chemotherapy (5-day course). Patients achieving complete remission will receive three consolidation courses of "V-TAD" and then no further therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This protocol was approved in September 1986. This study has accrued its target number of patients nationally and has been terminated. Remissions with this program were similar to standard dose "TAD".

Detail Summary Sheet

Prot No: SWOG 8565(86)	Status: Terminated
TITLE: Evaluation of Menogaril (NSC-269148) in Colorectal Carcinoma, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: carcinoma, colorectal	
Funding: FY 87: NA	FY 88: \$800.
Gifts: Menogaril	Periodic Review Date: Sep 88 Decision: Terminate

OBJECTIVE: To determine the response rate and response duration of advanced colorectal carcinoma to a new drug, menogaril.

TECHNICAL APPROACH: Patients agreeing to the study will all receive menogaril once a month as a one-hour IV infusion.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This protocol was approved in September 1986. This protocol has been terminated as it has accrued its target number of patients nationally. No partial or complete remissions were seen.

Detail Summary Sheet

Prot No: SWOG 8597(86)	Status: Terminated
TITLE: Randomized Phase III Intergroup Study of Supradiaphragmatic Irradiation in Stage II-A Seminoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; MAJ Luke Stapleton, MC Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC; LTC Aida Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: seminoma	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Sep 88
Gifts: none	Decision: Terminate

OBJECTIVE: To determine whether supradiaphragmatic radiation really adds anything to infradiaphragmatic radiation for stage II-A seminoma (i.e., enlarged retroperitoneal nodes on CT scan).

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive or not receive supradiaphragmatic radiation as part of their radiation for stage II-A seminoma.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This protocol was approved in September 1986. This study has been terminated due to poor patient accrual.

Detail Summary Sheet

Prot No: SWOG 8598 (87)	Status: Ongoing
TITLE: A Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation and Chemotherapy, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: esophagus, cancer, radiation, chemotherapy	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Mar 88
Gifts: none	Decision: Continue

OBJECTIVE: To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus. Specifically, to determine if the combination of chemotherapy and radiation will add to the overall survival and cure of patients treated with the combination when compared to patients treated by radiation alone.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive (1) radiation alone (6400 rads in 6½ weeks) or (2) radiation (5,000 rads in 5 weeks) beginning simultaneously with four cycles of chemotherapy (cisplatinum plus 5-FU).

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

One patient from Tripler entered. He was randomized to radiation alone and has completed treatment.

Detail Summary Sheet

Prot No: SWOG 8590(85) (previously 8591) Status: Ongoing

TITLE: Phase III Study to Determine the Effect of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck

Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: MAJ William Uphouse, MC;

Department/Section: Medicine/Adult Hematology-Oncology

Key Words: carcinoma, squamous cell

Funding: FY 87: NA FY 88: \$800. Periodic Review Date: Apr 88
Gifts: None Decision: Continue

OBJECTIVE: To determine if adding chemotherapy will improve results of surgery and radiation for advanced (Stage III and IV) but resectable head and neck cancer.

TECHNICAL APPROACH: All patients agreeing to participate in the study will be randomized to receive (1) surgery, then radiation therapy, or (2) surgery, then three cycles of chemotherapy (cisplatin plus 5-FU), then radiation.

PROGRESS: No. of Subjects Enrolled - To Date: 3 Reporting Period: 1

All three patients entered to date are doing well. One received chemotherapy. Further follow-up if needed and in the past these patients generally don't do well (without chemotherapy that is). The number of this protocol has been changed from 8591 to 8590.

Detail Summary Sheet

Prot No: SWOG 8594(86)	Status: Ongoing
TITLE: A Phase III Trial of Cis-platinum Alone or in Combination with Doxorubicin, Vinblastine and Methotrexate in Advanced Bladder Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: cancer, bladder	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jul 88 Decision: Continue

OBJECTIVE: To determine if cis-platinum in combination with doxorubicin, vinblastine, and methotrexate is more effective than cis-platinum alone in the treatment of patients with advanced bladder cancer in terms of objective response rate, response duration, and survival.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive either (1) cis-platinum IV every 28 days until disease progression or (2) cis-platinum, doxorubicin, vinblastine, and methotrexate IV every four weeks until disease progression.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Accrual to this study has been slow nationally but it's a very important study (i.e. do the other 3 drugs really add anything to cisplatin alone in metastatic bladder cancer).

Detail Summary Sheet

Prot No: SWOG 8600(87)	Status: Ongoing
TITLE: A Randomized Investigation of High Dose Versus Standard Dose Cytosine Arabinoside With Daunorubicin In Patients With Acute Non-Lymphocytic Leukemia	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: cytosine arabinoside and daunorubicin	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Feb 88
	Decision: Continue

OBJECTIVE: To compare, among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose cytosine arabinoside and daunorubicin or high dose cytosine arabinoside and daunorubicin. Also to compare these 2 programs when used in the consolidation phase.

TECHNICAL APPROACH: Patients are randomized to receive standard or high dose cytosine arabinoside initially. If remission is achieved then patients are randomized again to receive standard or high dose cytosine arabinoside for consolidation.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

This study was opened recently.

Detail Summary Sheet

Prot No: SWOG 8604(87)	Status: Terminated
TITLE: Evaluation of 6-Thioguanine (6-TG) in Refractory and Relapsing Myeloma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: 6-Thioguanine (6-TG); refractory or relapsing myeloma	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Apr 88
	Decision: Terminate

OBJECTIVE: To determine the antitumor activity of 6-Thioguanine (6-TG) in patients with refractory or relapsing myeloma.

TECHNICAL APPROACH: Patients agreeing to participate will receive 6-TG as an IV infusion over several minutes every three weeks until relapse.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has been terminated as it has accrued its target number of patients nationally. No partial or complete responses were seen.

Detail Summary Sheet

Prot No: SWOG 8605 (86)	Status: Ongoing
TITLE: Cyclophosphamide, Ara-C Infusion and Vincristine for Relapsed or Refractory Extensive Small Cell Lung Cancer, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ L. M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC; MAJ Marianne M. Young, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Lung cancer; small cell	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Feb 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine the efficacy of a new chemotherapy combination in relapsing or refractory small cell lung cancer.

TECHNICAL APPROACH: Patients agreeing to participate will receive cytoxan and Ara-C every 3 weeks for four cycles, then prophylactic cranial irradiation, then two more cycles of the chemotherapy. Vincristine will also be given with the other two drugs.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

The study remains open. One of the two TAMC patients achieved a near complete remission of his relapsed extensive small cell lung cancer and is doing well.

Detail Summary Sheet

Prot No: SWOG 8611(87)	Status: Ongoing
TITLE: A Randomized Trial of Two Schedules of Trimetrexate versus 5-Fluorouracil in Colorectal Carcinoma, Phase II-III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Trimetrexate vs. 5-Fluorouracil in Colorectal Carcinoma	
Funding: FY 87: NA	FY 88: \$800.
Periodic Review Date: Feb 88	
Gifts: None	Decision: Continue

OBJECTIVE: To determine and compare the response rates, response durations and toxicities of trimetrexate given on two different schedules to patients with advanced colorectal cancer. Also to compare patient survival on trimetrexate versus that on 5FU.

TECHNICAL APPROACH: Patient agreeing to participate in the study are randomized to receive trimetrexate by either of 2 IV schedules on to receive 5FU IV.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

The one TAMC patient has been randomized to receive trimetrexate and has had stable disease with this on follow-up CT scan. The study remains open.

Detail Summary Sheet

Prot No: SWOG 8616(87)	Status: Ongoing
TITLE: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine With or Without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: ifosfamide, mesna	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88
	Decision: Continue

OBJECTIVE: To determine if adding ifosfamide and mesna to the usually employed drugs of doxorubicin and dacarbazine will improve the response rate, response duration and survival in metastatic soft tissue and bone sarcoma.

TECHNICAL APPROACH: Patients agreeing to participate will have a central line (port-a-cath) placed and receive 4 days of doxorubicin and dacarbazine continuously through this line. These patients will also be randomized to receive or not receive 4 days of therapy with ifosfamide and mesna. These latter drugs are given together through a peripheral IV (in patients randomized to receive them). This whole chemotherapy regimen is repeated every 3 weeks until disease progression is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

This study just opened for patient accrual. The one TAMC patient entered has had stabilization of his disease with the 4 drug arm.

Detail Summary Sheet

Prot No: SWOG 8617(87)	Status: Ongoing
TITLE: Evaluation of Interleukin 2 in Metastatic Renal Cell Carcinoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: Metastatic Renal Cell Carcinoma	
Funding: FY 87: NA	FY 88: \$800.
Gifts: Interleukin 2	Periodic Review Date: Aug 88
	Decision: Continue

OBJECTIVE: To determine the response rate and the remission duration in metastatic renal cell carcinoma treated with Interleukin 2.

TECHNICAL APPROACH: Patients agreeing to participate in this study will receive Interleukin 2 by IV bolus three times a week until disease progression is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 1

One TAMC patient has been enrolled and has had almost complete resolution of her pulmonary metastases. The study remains open.

Detail Summary Sheet

Prot No: SWOG 8624(87)	Status: Ongoing
TITLE: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma (1) Comparison of VMCP/VBAP to VAD or VMCP/VBAPP for Induction; (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha-2b Interferon + Dexamethasone for Incomplete or Non-Responders	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: multiple myeloma; Alpha-2b interferon	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: None	Decision: Continue

OBJECTIVE: (1) To compare SWOG's best induction chemotherapy program for myeloma with two other very promising programs; (2) to determine if interferon is a better maintenance program than no treatment; and (3) to determine if interferon plus decadron can salvage patients who do not respond satisfactorily to the above induction programs.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive one of the three induction programs. Those who achieve a response (75% M-protein reduction) will be randomized to receive or not receive interferon. Those not achieving response will be offered the above salvage program.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients entered but study is still new. There are no data available yet.

Detail Summary Sheet

Prot No: SWUG 8632(87) Status: Ongoing
TITLE: Evaluation of Echinomycin in Central Nervous Systems Tumors, Phase II
Principal Investigator: COL Jeffrey Berenberg, MC
Associate Investigators: MAJ William J. Uphouse, MC
Department/Section: Medicine/Adult Hematology-Oncology
Key Words: Echinomycin
Funding: FY 87: NA FY 88: \$800. Periodic Review Date: Aug 88
Gifts: Echinomycin Decision: Continue

OBJECTIVE: To assess the efficacy of echinomycin in recurrent or residual central nervous system tumors by evaluation of response rate, response duration, and survival.

TECHNICAL APPROACH: Patients agreeing to participate in the study will receive courses of treatment (once a week IV for 4 weeks then 2 weeks rest) until disease progression is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has just opened. There are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8642(87)	Status: Ongoing
TITLE: Recombinant Human Interferon-Gamma for the Adjuvant Treatment of High Risk Malignant Melanoma after Surgical Excision of the Primary Lesion, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: Recombinant Human Interferon-Gamma	
Funding: FY 87: NA	FY 88: \$800.
Periodic Review Date: Aug 88	
Gifts: Recombinant Human Interferon-Gamma	
Decision: Continue	

OBJECTIVE: To compare the survival and disease-free survival among patients who are at high risk for recurrence of melanoma following resection of all known disease, and who are randomized to receive recombinant human interferon-gamma adjuvant therapy or no adjuvant therapy.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive or not receive interferon-gamma subcutaneously once a day for 12 months.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has just opened. There are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8703(88)	Status: Ongoing
TITLE: Evaluation of Vinblastine and High-Dose Cis-platinum in the Treatment of Advanced Non-small Cell Lung Carcinoma, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: vinblastine;	
Funding: FY 87: NA FY 88: \$800.	Periodic Review Date: Apr 88
Gifts: None	Decision: Continue

OBJECTIVE: To determine the activity of a new program of combination chemotherapy in the treatment of advanced non-small cell lung cancer.

TECHNICAL APPROACH: Patient agreeing to participate will receive Cis-platinum 100 mg/M² and Vinblastine on day 1 and 8 each month for 3 months and then no further treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

This study has opened recently and one of the two TAMC patients has had a 30% tumor reduction with this program. His tumor filled almost his entire left lung initially. The second patient had no response.

Detail Summary Sheet

Prot No: SWOG 8712(88)	Status: Ongoing
TITLE: A Phase II Trial of Trimetrexate in the Treatment of Hepatoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: trimetrexate; hepatoma	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: May 88
	Decision: Continue

OBJECTIVE: To determine the efficacy of Trimetrexate, a new drug, in unresectable hepatoma.

TECHNICAL APPROACH: Patients agreeing to participate will receive Trimetrexate daily for 5 days IV every 3 weeks until disease progresses.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

This study is still open. No results are available yet.

Detail Summary Sheet

Prot No: SWOG 8736(88)	Status: Ongoing
TITLE: Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medical Hematology-Oncology Service, Department of Medicine	
Key Words: Non-Hodgkin's Lymphoma;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88
	Decision: Continue

OBJECTIVE: To compare the survival rates and toxicity of two curative approaches in patients with localized (stage I & II), intermediate or high grade non-Hodgkin's lymphoma.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive either 1) 8 cycles of chemotherapy (CHOP) or 2) 3 cycles of CHOP and then 4000 rads of radiation to the involved area.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has just opened. There are no data available yet.

Detail Summary Sheet

Proj No: SWOG 8738(88)	Status: Ongoing
TITLE: Treatment of Extensive Non-Small Cell Lung Cancer: Standard Dose Cisplatin vs High-Dose Cisplatin in Hypertonic Saline Alone vs High-Dose Cisplatin/Mitomycin-C	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology Service	
Key Words: cisplatin;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88
	Decision: Continue

OBJECTIVE: To compare standard dose Cisplatin chemotherapy to high-dose Cisplatin alone and to high-dose Cisplatin plus Mitomycin-C in a randomized study with attention to response rate, response duration and survival in metastatic non-small cell lung cancer.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to 1) 8 cycles of standard dose Cisplatin (50mg/M² Day 1 and 8) or 2) 4 cycles of high-dose Cisplatin (100mg/M² Day 1 and 8) or 3) 4 cycles of high-dose Cisplatin (as above) plus Mitomycin-C.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has just opened. No data are available yet.

Detail Summary Sheet

Prot No: SWOG 8804(88)	Status: Ongoing
TITLE: Evaluation of Cis-platinum and DTIC in Inoperable Stage III and Stage IV Melanoma	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medical Hematology-Oncology Service, Department of Medicine	
Key Words: cis-platinum; DTIC; advanced melanoma;	
Funding: FY 87: NA	FY 88: \$500.
Gifts: None	Periodic Review Date: Jun 88
	Decision: Continue

OBJECTIVE: To determine the response rate and efficacy of DTIC plus Cis-platinum in inoperable advanced melanoma.

TECHNICAL APPROACH: Patients agreeing to participate will receive DTIC and Cis-platinum IV day 1 every 3 weeks until progressive disease is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

There is no data available yet on this study at the national level.

Detail Summary Sheet

Prot No: SWOG 8805(88)	Status: Ongoing
TITLE: Neoadjuvant Cisplatin and VP-16 Plus Concurrent Chest and Brain Irradiation for Patients with Stage III Non-Small Cell Lung Carcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology Svc	
Key Words: Cisplatin; VP-16;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Aug 88 Decision: Continue

OBJECTIVE: To assess the response rate, resectability rate and, ultimately, survival in patients with locally advanced non-small cell lung cancer treated with simultaneous chemotherapy and radiation prior to assessment for possible surgery. The benefit of prophylactic cranial radiation will also be examined.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 2 cycles of Cisplatin and VP-16 plus simultaneous chest and cranial radiation therapy. If they are then considered resectable, they will then have a thoracotomy with resection.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has just opened. No data are available yet.

Detail Summary Sheet

Prot No: SWOG 8793(88)	Status: Ongoing
TITLE: Randomized Phase III Evaluation of Hormonal Therapy vs. Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medical Hematology-Oncology Service, Department of Medicine	
Key Words: hormonal therapy; pelvic lymphadenectomy; radical prostatectomy	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88
	Decision: Continue

OBJECTIVE: To compare the time to progression and the survival time for patients with resected stage D1 (positive lymph nodes) prostate cancer when they receive immediate hormone therapy vs. hormone therapy when the disease progresses.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be assigned to receive hormone therapy or observation. If they are assigned to the hormone therapy arm, the patient may choose either orchiectomy or zoladex (a hormone which given qmon SQ produces castrate testosterone levels and has no serious side effects).

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has just opened recently. No data are available yet.

Detail Summary Sheet

Prot No: SWOG 8810(88)	Status: Ongoing
TITLE: Six Courses of 5-FU and Cis-platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinomas of the Head and Neck, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medical Hematology-Oncology Service, Department of Medicine	
Key Words: squamous cell carcinomas;	
Funding: FY 87: NA	FY 88: \$800.
Gifts: None	Periodic Review Date: Jun 88
	Decision: Continue

OBJECTIVE: To determine if 6 cycles of Cis-platinum plus 5-FU will result in more complete remissions of locally advanced head and neck cancer than 3 cycles.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 3 cycles of Cis-platinum plus 5-FU. Patient who then achieve at least a partial remission (50% or more tumor shrinkage) will get 3 additional cycles. With less than partial, come off study.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study has just opened. There are no data available yet.

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